"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, which shall not be either the specific chemical identity or a structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by their unique identifiers, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to a chemical substance included on the list published under subparagraph (B) while the specific chemical identity of the chemical substance is protected from disclosure under this section identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of a specific chemical identity that has been denied by

the Administrator or expired, or that has been withdrawn by the person who asserted the claim, and for which the Administrator has used a unique identifier assigned under this paragraph to protect the specific chemical identity in information that the Administrator has made public, clearly link the specific chemical identity to the unique identifier in such information to the extent practicable.

"(h) CRIMINAL PENALTY FOR WRONGFUL DISCLOSURE.—

"(1) INDIVIDUALS SUBJECT TO PENALTY.—

"(A) IN GENERAL.—Subject to subparagraph (C) and paragraph (2), an individual described in subparagraph (B) shall be fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—An individual referred to in subparagraph (A) is an individual who—

"(i) pursuant to this section, obtained possession of, or has access to, information protected from disclosure under this section; and

"(ii) knowing that the information is protected from disclosure under this section, willfully discloses the information in any manner to any person not entitled to receive that information.

"(C) EXCEPTION.—This paragraph shall not apply to any medical professional (including an emergency medical technician or other first responder) who discloses any information obtained under paragraph (5) or (6) of subsection (d) to a patient treated by the medical professional, or to a person authorized to make medical or health care decisions on behalf of such a patient, as needed for the diagnosis or treatment of the patient.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported ~~to or otherwise obtained~~ to or otherwise obtained by the Administrator under this Act.

"(i) APPLICABILITY.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applica-

ble Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or re-substantiation of a claim for the protection from disclosure of information reported to or otherwise obtained by the Administrator under this Act prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or re-substantiation requirements, with respect to the protection of information described in subsection (a), under this Act that are more extensive than those required under this section.

"(2) ACTIONS PRIOR TO PROMULGATION OF RULES.—Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or re-substantiation of, or approving, approving in part, or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(j) ACCESS BY CONGRESS.—Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this Act shall be made available, upon written request of any duly authorized committee of the Congress, to such committee.".

SEC. 2019. CONFORMING AMENDMENTS.

(a) TABLE OF CONTENTS.—The table of contents in section 1 of the Toxic Substances Control Act is amended—

(1) by striking the item relating to section 6 and inserting the following:

"Sec. 6. Prioritization, risk evaluation, and regulation of chemical substances and mixtures.";

(2) by striking the item relating to section 10 and inserting the following:

"Sec. 10. Research, development, collection, dissemination, and utilization of information.";

(3) by striking the item relating to section 14 and inserting the following:

"Sec. 14. Confidential information."; and

(4) by striking the item relating to section 25.

(b) SECTION 2.—Section 2(b)(1) of the Toxic Substances Control Act (15 U.S.C. 2601(b)(1)) is amended by striking "data" both places it appears and inserting "information".

(c) SECTION 3.—Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) in paragraph (8) (as redesignated by section 3 of this Act), by striking "data" and inserting "information"; and

(2) in paragraph (15) (as redesignated by section 3 of this Act)—

(A) by striking "standards" and inserting "protocols and methodologies";

(B) by striking "test data" both places it appears and inserting "information"; and

(C) by striking "data" each place it appears and inserting "information".

(d) SECTION 4.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) in subsection (b)—

(A) in paragraph (1), by striking "rule" each place it appears and inserting "rule, order, or consent agreement";

(B) in paragraph (2)(B), by striking "rules" and inserting "rules, orders, and consent agreements"; and

(C) in paragraph (3)(A), by striking "rule" and inserting "rule or order"; and

(D) in paragraph (4)—

(i) by striking "rule under subsection (a)" each place it appears and inserting

"rule, order, or consent agreement under subsection (a)";

(ii) by striking "repeals the rule" each place it appears and inserting "repeals the rule or order or modifies the consent agreement to terminate the requirement"; and

(iii) by striking "repeals the application of the rule" and inserting "repeals or modifies the application of the rule, order, or consent agreement";

(2) in subsection (c)—

(A) in paragraph (1), by striking "rule" and inserting "rule or order";

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "a rule under subsection (a) or for which data is being developed pursuant to such a rule" and inserting "a rule, order, or consent agreement under subsection (a) or for which information is being developed pursuant to such a rule, order, or consent agreement";

(ii) in subparagraph (B), by striking "such rule or which is being developed pur-

suant to such rule" and inserting "such rule, order, or consent agreement or which is being developed pursuant to such rule, order, or consent agreement"; and

(iii) in the matter following subparagraph (B), by striking "the rule" and inserting "the rule or order";

(C) in paragraph (3)(B)(i), by striking "rule promulgated" and inserting "rule, order, or consent agreement"; and

(D) in paragraph (4)—

(i) by striking "rule promulgated" each place it appears and inserting "rule, order, or consent agreement";

(ii) by striking "such rule" each place it appears and inserting "such rule, order, or consent agreement"; and

(iii) in subparagraph (B), by striking "the rule" and inserting "the rule, order, or consent agreement";

(3) in subsection (d), by striking "rule" and inserting "rule, order, or consent agreement"; and

(4) in subsection (g), by striking "rule" and inserting "rule, order, or consent agreement".

Commented [A32]: We think this should say "the rule or order", not "the rule, order or consent agreement". The rest of (c) indicates that only parties to rule and orders can get exemptions (although they can get them based on info submitted under rules, orders, or consent agreements). So the inclusion of consent agreement here seems wrong, since this provision is discussing the requirements as to which an exemption has been granted.

(e) SECTION 5.—Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) in subsection (b)—

(A) in paragraph (1)(A)—

(i) by striking "rule promulgated" and inserting "rule, order, or consent agreement"; and

(ii) by striking "such rule" and inserting "such rule, order, or consent agreement";

(B) in paragraph (1)(B)—

(i) by striking "rule promulgated" and inserting "rule or order"; and

(ii) by striking "the date of the submission in accordance with such rule" and inserting "the required date of submission"; and

(C) in paragraph (2)(A)(ii), by striking "rule promulgated" and inserting "rule, order, or consent agreement"; and

(2) in subsection (d)(2)(C), by striking "rule" and inserting "rule, order, or consent agreement".

(f) SECTION 7.—Section 7(a)(1) of the Toxic Substances Control Act (15 U.S.C. 2606(a)(1)) is amended, in the matter following subparagraph (C), by striking "a

rule under section 4, 5, 6, or title IV or an order under section 5 or title IV" and inserting "~~(~~a~~)~~a determination under section 5 or 6~~,~~, a rule under section 4, 5, or 6 or title IV, an order under section 4~~,~~ 5~~,~~ or ~~5~~6 or title IV, or ~~a~~ a consent agreement under section 4". ~~(does this need to pull in 6(i) orders?),~~

(g) SECTION 8.—Section 8(a) of the Toxic Substances Control Act (15 U.S.C. 2607(a)) is amended—

(1) in paragraph (2)(E), by striking "data" and inserting "information"; and

(2) in paragraph (3)(A)(ii)(I), by striking "or an order in effect under section 5(e)" and inserting ", an order in effect under section 4 or 5(e), or a consent agreement under section 4". ~~(does this need to pull in 6(i) orders?),~~

(h) SECTION 9.—Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

~~(~~(1) in subsection (a), by striking "section 6" each place it appears and inserting "section 6(a)"; and~~,~~

(2) in subsection (d), by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

(i) SECTION 10.—Section 10 of the Toxic Substances Control Act (15 U.S.C. 2609) is amended—

(1) in the section heading, by striking "**DATA**"

and inserting "**INFORMATION**";

(2) by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services";

(3) in subsection (b)—

(A) in the subsection heading, by striking "DATA" and inserting "INFORMATION";

(B) by striking "data" and inserting "information" in paragraph (1);

(C) by striking "data" and inserting "information" in paragraph (2)(A); and

(D) by striking "a data" and inserting "an information" in paragraph (2)(B); and

(4) in subsection (g), by striking "data" and inserting "information".

(j) SECTION 11.—Section 11(b)(2) of the Toxic Substances Control Act (15 U.S.C. 2610(b)(2)) is amended—

(1) by striking "data" each place it appears and inserting "information"; and

(2) in subparagraph (E), by striking "rule promulgated" and inserting "rule promulgated, order issued, or consent agreement entered into".

(k) SECTION 12.—Section 12(b)(1) of the Toxic Substances Control Act (15 U.S.C. 2611(b)(1)) is amended by striking "data" both places it appears and inserting "information".

(l) SECTION 15.—Section 15(1) of the Toxic Substances Control Act (15 U.S.C. 2614(1)) is amended by striking "(A) any rule" and all that follows through "or (D)" and inserting "any requirement of this title or any rule promulgated, order issued, or consent agreement entered into under this title, or".

(m) SECTION 19.—Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)(A)—

(i) by striking "Not later than 60 days after the date of the promulgation of a rule under section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting "Except as otherwise provided in this title, not later than 60 days after the date on which a rule is promulgated under this title, title II, or title IV, or the date on which an order is issued under section 4, 5(e), 5(f), or 6(i)(1),";

(ii) by striking "such rule" and inserting "such rule or order"; and

(iii) by striking "such a rule" and inserting "such a rule or order";

(B) in paragraph (1)(B)—

(i) by striking "Courts" and inserting "Except as otherwise provided in this title, courts"; and

(ii) by striking "subparagraph (A) or (B) of section 6(b)(1)" and inserting "this title, other than an order under section 4, 5(e), 5(f), or 6(i)(1),"; and

(C) in paragraph (2), by striking "rule-making record" and inserting "record"; and

(2) in subsection (b)—

(A) by striking "review a rule" and inserting "review a rule, or an order under section 4, 5(e), 5(f), or 6(i)(1),";

(B) by striking "such rule" and inserting "such rule or order";

(C) by striking "the rule" and inserting "the rule or order";

(D) by striking "new rule" each place it appears and inserting "new rule or order"; and

(E) by striking "modified rule" and inserting "modified rule or order"; and

(3) in subsection (c)—

(A) in paragraph (1)—

(i) in subparagraph (A)—

(I) by striking "a rule" and inserting "a rule or order"; and

(II) by striking "such rule" and inserting "such rule or order";

(ii) in subparagraph (B)—

(I) in the matter preceding clause (i), by striking "a rule" and inserting "a rule or order";

(II) by amending clause (i) to read as follows:

"(i) in the case of review of—

"(I) a rule under section 4(a), 5(b)(4), 6(a) (including review of the associated determination under section 6(b)(4)(A)), or 6(e), the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole; and

"(II) an order under section 4 ~~or 6(i)(1~~, 5(e), 5(f), or 6(i)(1), the standard for review prescribed by ~~paragraph~~paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such order if the court finds that the

order is not supported by substantial evidence in the record taken as a whole; and"; and

(III) by striking clauses (ii) and (iii) and the matter after clause (iii) and inserting the following:

"(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule or order, except as part of the record, taken as a whole."; and

(iii) by striking subparagraph (C); and

(B) in paragraph (2), by striking "any rule" and inserting "any rule or order".

(n) SECTION 20.—Section 20(a)(1) of the Toxic Substances Control Act (15 U.S.C. 2619(a)(1)) is amended by striking "order issued under section 5" and inserting "order issued under section 4 or 5". ~~*ϕdoes this need to pull in 6(i) orders?*~~

(o) SECTION 21.—Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "order under section 5(e) or (6)(b)(2)" and inserting "order under section 4 or 5(e) or (f)"; and ~~*ϕdoes this need to pull in 6(i) orders?*~~

(2) in subsection (b)—

(A) in paragraph (1), by striking "order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "order under section 4 or 5(e)~~or (f)~~"; and

~~*does this need to pull*~~(B) in paragraph (4)(B)—

(i) in the matter preceding clause (i), by striking "order under section 5(e) or 6(b)(2)" and inserting "order under section 4 or 5(e)";

(ii) in clause (i), by striking "order under section 5(e)" and inserting "order under section 4 or 5(e)"; and

(iii) in clause (ii), by striking "or an order under section 6(~~*i) orders?*~~; b)(2)".

(p) SECTION 24.—Section 24(b)(2)(B) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)) is amended—

(1) by inserting "and" at the end of clause (i);

(2) by striking clause (ii); and

(3) by redesignating clause (iii) as clause (ii).

(q) SECTION 26.—Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) in subsection (e), by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services"; and

(2) in subsection (g)(1), by striking "data" and inserting "information".

(r) SECTION 27.—Section 27(a) of the Toxic Substances Control Act (15 U.S.C. 2626(a)) is amended—

(1) by striking "Health, Education, and Welfare" and inserting "Health and Human Services";

(2) by striking "test data" both places it appears and inserting "information";

(3) by striking "rules promulgated" and inserting "rules, orders, or consent agreements"; and

(4) by striking "standards" and inserting "protocols and methodologies".

(s) SECTION 30.—Section 30(2) of the Toxic Substances Control Act (15 U.S.C. 2629(2)) is amended by striking "rule" and inserting "rule, order, or consent agreement".

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/4/2016 9:19:21 PM
To: 'McCarthy, David' [David.McCarthy@mail.house.gov]
CC: 'Cohen, Jacqueline' [jackie.cohen@mail.house.gov]
Subject: RE: HEC TSCA TA request on 5/4 draft

Dave,
We're going through it tonight – will have response first thing in the morning. Okay? Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Wednesday, May 04, 2016 4:40 PM
To: 'McCarthy, David' <David.McCarthy@mail.house.gov>
Cc: Cohen, Jacqueline <jackie.cohen@mail.house.gov>
Subject: HEC TSCA TA request on 5/4 draft

Dave – checking on timing for when you need the TA. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: McCarthy, David [mailto:David.McCarthy@mail.house.gov]
Sent: Wednesday, May 04, 2016 3:50 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Cohen, Jacqueline <jackie.cohen@mail.house.gov>
Subject: TA request

Dear Sven,

The attached draft of the TSCA compromise text incorporates changes to the April 22 draft we've discussed over the last couple days. Just want to confirm with you that, as you see it whole, you think it's language that you can implement. In particular, will you know how to administer Section 5 as drafted? Does it clearly provide that an affirmative action by EPA is needed before a manufacturer may begin manufacturing? Is that decision risk-based? In Section 6 will EPA be able to implement the prioritization provision? Are EPA's choices clear at the end of the prioritization phase? In Section 26, do you understand what your discretion and limitations are in setting, collecting, and using user fees?

Thanks so much. Dave

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/25/2016 8:15:06 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Leg History - Fees

Michal,
We are reviewing the draft leg history document and will have the requested TA for you shortly. Attached are two suggestions related to fees that EPA believes would be useful to add to the document. The first relates how fees are collected and used to defray the cost of specific activities. The second relates to a new issue spotted – a reference that could be interpreted to exclude the cost of EPA risk evaluations from the costs that can be covered by fees.

1. Fees under section 26(b) are authorized to be collected so that 25% of EPA's overall costs to carry out section 4, 5, and 6, and to collect, process, review, provide access to and protect from disclosure information, are defrayed, subject to a $25,000,000 cap. While the collection of fees is tied to the submission of particular information or the manufacturing or processing of a particular chemical substance undergoing a risk evaluation, in general the use of these fees is not limited to defraying the cost of the action that was the basis for the fee. The exception to this general principle is for fees to defray the cost of conducting manufacturer requested risk evaluations. These must be spent on the particular risk evaluation that was the basis for the fee. This limitation applies only to the fee collected for purpose of conducting the risk evaluation and does not prevent EPA from collecting further fees from such persons for other appropriate uses under the section. For example, if that risk evaluation later leads to risk management action, EPA may assign further fees to manufacturers and processors of that substance, subject to the $25,000,000 cap and the requirement to not exceed 25% of overall program costs for carrying out sections 4, 5, and 6.

2. We note that section 26(b)(4)(B)(i)(I) could be read to exclude the cost of risk evaluations, other than industry-requested risk evaluations, from the costs that can be covered by fees. This was not the intent. As clearly indicated in section 26(b)(1), Congress intends that manufacturers and processors of chemicals subject to risk evaluations (among other entities) be subject to fees, and that fees be collected to defray the cost of administering sections 4, 5, and 6. Risk evaluations are a central element of section 6. And as demonstrated by section 6(b)(4)(F)(i), the intent of the bill is that the EPA-initiated risk evaluations be defrayed at the 25% level (subject to the $25,000,000 cap), in contrast to the industry-initiated evaluations, which are funded at the 50% or 100% level. The final citation in section 26(b)(4)(B)(i) should be to section 6(b)(4)(C)(ii), as it is in section 6(b)(4)(F)(i), not to section 6(b) generally.

Please let me know if any questions. Thanks,
Sven

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/4/2016 8:19:20 PM
To: McCarthy, David [David.McCarthy@mail.house.gov]
CC: Cohen, Jacqueline [jackie.cohen@mail.house.gov]
Subject: HEC TSCA TA request on 5/4 draft

Dave- got it. We are on it and will turn around the TA as soon as possible. Thanks,
Sven

On May 4, 2016, at 3:49 PM, McCarthy, David <David.McCarthy@mail.house.gov> wrote:

Dear Sven,

The attached draft of the TSCA compromise text incorporates changes to the April 22 draft we've discussed over the last couple days. Just want to confirm with you that, as you see it whole, you think it's language that you can implement. In particular, will you know how to administer Section 5 as drafted? Does it clearly provide that an affirmative action by EPA is needed before a manufacturer may begin manufacturing? Is that decision risk-based? In Section 6 will EPA be able to implement the prioritization provision? Are EPA's choices clear at the end of the prioritization phase? In Section 26, do you understand what your discretion and limitations are in setting, collecting, and using user fees?

Thanks so much. Dave
<2016_03_xml.pdf>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/25/2016 5:20:06 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA - section 9

Michal - please see TA responding to House floor debate yesterday on section 9 and section 6 (Blackburn, Pittenger). Please let me know if any questions. Thanks,
Sven

EPA's authorities and duties under section 6 have been significantly expanded, now including comprehensive deadlines and throughput expectations for chemical prioritization, risk evaluation, and risk management. The interagency referral process and the intra-agency consideration process established under Section 9 must now be regarded in a different light since TSCA can no longer be construed as a "gap-filler" authority of last resort. Accordingly, section 9 has been revised to ensure that once it is clear that a chemical substance presents an unreasonable risk, these processes will not conflict with the fundamental expectation that EPA timely ensure that the chemical substance no longer presents such risk.

The question of whether existing regulation of a chemical substance (either by EPA or other authorities) adequately mitigates the risks of a chemical substance is one that EPA would consider in the course of its risk evaluation under Section 6. It is not a separate factor that EPA may invoke under Section 9 to allow unreasonable risks to persist. Once EPA has identified that a chemical substance presents an unreasonable risk, Section 9(a) is not intended to supersede or modify the Agency's obligations under 6(a) or 7 to address risks from activities involving the chemical substance, except as expressly identified in a section 9(a) referral for further regulation by another agency.

Regarding EPA's consideration of whether to use non-TSCA EPA authorities in order to address unreasonable chemical risks identified under TSCA, the new section 9(b)(2) merely consolidates existing language which was previously split between section 6(c) and section 9(b). It only applies where the Administrator has already determined that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by additional actions taken under other EPA authorities. It allows the Administrator substantial discretion to use TSCA nonetheless, and it certainly does not reflect that TSCA is an authority of last resort in such cases. Furthermore, none of these revisions were intended to alter the clear intent of Congress, reflected in the original legislative history of TSCA, that these decisions would be completely discretionary with the Administrator and not subject to judicial review in any manner.

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Mrs. BLACKBURN. Mr. Speaker, I do rise in support of the amendments to H.R. 2576, and I congratulate Chairman *Shimkus* on the wonderful job he has done.

Mr. Speaker, I yield to the gentleman from Illinois (Mr. *Shimkus*) for the purpose of a brief colloquy to clarify one important element of the legislation.

Mr. Chairman, it is my understanding that this bill reemphasizes Congress' intent to avoid duplicative regulation through the TSCA law. It does so by carrying over two important EPA

constraints in section 9 of the existing law while adding a new, important provision that would be found as new section, 9(b)(2).

It is my understanding that, as a unified whole, this language, old and new, limits the EPA's ability to promulgate a rule under section 6 of TSCA to restrict or eliminate the use of a chemical when the Agency either already regulates that chemical through a different statute under its own control and that authority sufficiently protects against a risk of injury to human health or the environment, or a different agency already regulates that chemical in a manner that also sufficiently protects against the risk identified by EPA.

Would the chairman please confirm my understanding of section 9?

Mr. SHIMKUS. Will the gentlewoman yield?

Mrs. BLACKBURN. I yield to the gentleman from Illinois.

Mr. SHIMKUS. The gentlewoman is correct in her understanding.

Mrs. BLACKBURN. I thank the chairman. The changes you have worked hard to preserve in this negotiated bill are important. As the EPA's early-stage efforts to regulate methylene chloride and TCE under TSCA statute section 6 illustrate, they are also timely.

EPA simply has to account for why a new regulation for methylene chloride and TCE under TSCA is necessary since its own existing regulatory framework already appropriately addresses risk to human health. New section 9(b)(2) will force the Agency to do just that.

---

* * *

Mr. SHIMKUS. Mr. Speaker, I yield 2 minutes to the gentleman from North Carolina (Mr. *Pittenger*).

Mr. PITTENGER. Mr. Speaker, I thank the chairman for this very sensible legislation. I appreciate his efforts in leading a bipartisan effort to reform U.S. chemical safety law that is decades in the making.

I particularly thank him for securing amendments to section 9 of the TSCA law that remain in the negotiated text. These amendments reemphasize and strengthen Congress' intent that TSCA serve as an authority of last resort for the regulation of a chemical when another authority under EPA's jurisdiction, or another Federal agency, already regulates the chemical and the risk identified by EPA.

As a unified whole, TSCA now makes clear that EPA may not promulgate a rule under section 6 of TSCA to restrict or eliminate the use of a chemical when:

Number one, the agency either already regulates that chemical through a different statute under its own control, like the Clean Air Act, and that authority sufficiently protects against a risk of injury to human health or the environment; or

Number two, a different agency already regulates that chemical in a manner that also sufficiently protects against the risk already identified by EPA.

Mr. Speaker, in light of yet another regulatory overreach in the rulemaking at EPA, the new amendments to section 9 of TSCA are a welcome reform with the intent that it will help restrain the agency's unnecessary activities. These are commonsense, but important, protections given what EPA is likely to pursue.

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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/4/2016 7:28:02 PM
To: 'Richards, Tina' [Tina.Richards@mail.house.gov]; Couri, Jerry [JerryCouri@mail.house.gov]; McCarthy, David [David.McCarthy@mail.house.gov]
Subject: HEC TSCA TA request on chemical substance definition

Tina,
This TA responds to the request on the definition of chemical substance in the nomenclature savings clause.

Per our phone conversation, we understand HLC's concern with adding a reference to the chemical substance definition in just one place in TSCA. On the call, we discussed inserting the key language from the definition (a substance of a particular molecular identity) into the savings clause in lieu of incorporating the definition. On reflection, we don't think that will work, because the definition functions as an integrated whole and it would create problems to incorporate only a portion of it. Therefore, we retract our suggestion and think the savings clause should be left as is. Although there could be some value to explicitly referencing the definition – i.e. to avoid arguments as to whether a chemical substance had been manufactured pre-FRL – we think the downsides of referencing or copying portions of the definition probably outweigh the upsides.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Richards, Tina [mailto:Tina.Richards@mail.house.gov]
Sent: Wednesday, May 04, 2016 1:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Couri, Jerry <JerryCouri@mail.house.gov>; McCarthy, David <David.McCarthy@mail.house.gov>
Subject: Re: HEC TSCA TA request Re: Section 6(d)

One last thing - could you guys give us the explanation one more time why we need the citation to the definition of chemical substance in the nomenclature savings clause? HLC doesn't want to put "section 3(2)" in and they wanted to know the explanation and none of us could exactly recall it

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/25/2016 5:08:44 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA leg history request - partial RE language

Got it – we're on it

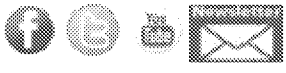
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, May 25, 2016 1:06 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA leg history request - partial RE language

No, but hotline went out and there is an NDAA tantrum on the floor right now. I want to share this doc w the other 3 senate Ds to get sign-on so want it asap, in case we are tonight or first thing tomorrow

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, May 25, 2016 1:04 PM
To: Freedhoff, Michal (Markey)
Subject: RE: Sen. Markey TSCA leg history request - partial RE language

Thanks – any word on when vote?

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

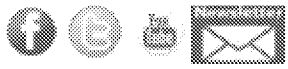
From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, May 25, 2016 1:02 PM

To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA leg history request - partial RE language

Ty. section is a bit rewritten but have added sentiment in new placement

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, May 25, 2016 12:57 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA leg history request - partial RE language

Michal,
This TA responds to the leg history request on partial risk evaluations. EPA suggests the following addition (in red):

Section 26(l)(4) states
''(4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.—With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6."

EPA has completed risk assessments on TCE, NMP, and MC, but has not yet proposed or finalized section 6(a) rules to address the risks that were identified. During the bicameral negotiations, EPA conveyed its concern that these risk assessments were not conducted across all conditions of use of these chemical substances, since existing TSCA does not require this to be done. EPA was concerned that if it proposed 6(a) rules to regulate these substances after TITLE was enacted, the rules could be invalidated through litigation because the risk assessments did not consider all conditions of use, and additionally noted the concern, which Congress shares, that if EPA delayed its rules for these substances in order to conduct a full risk evaluation across all conditions of use that the imposition of important public health protections that are known to be needed would also be delayed. The language House-Senate negotiators included above is intended to allow EPA to proceed with the regulation of these substances if the scope of the proposed and final rules is consistent with the scope of the risk assessments conducted on these substances (even though the risk assessments did not include a consideration of all conditions of use).

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460

202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: May 25, 2016 at 11:29:41 AM EDT
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: partial RE lanaguge

Section 26(l)(4) states
"(4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.—With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6."

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Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/4/2016 6:41:29 PM
To: 'Richards, Tina' [Tina.Richards@mail.house.gov]; Couri, Jerry [JerryCouri@mail.house.gov]; McCarthy, David [David.McCarthy@mail.house.gov]
Subject: FW: Urgent- HEC TSCA TA on Section 6(d)

Resend with RLSO showing

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Grant, Brian
Sent: Wednesday, May 04, 2016 1:39 PM
To: Berol, David <Berol.David@epa.gov>; Jones, Jim <Jones.Jim@epa.gov>; Mclean, Kevin <Mclean.Kevin@epa.gov>
Cc: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Schmit, Ryan <schmit.ryan@epa.gov>; Flattery, Priscilla <Flattery.Priscilla@epa.gov>; Distefano, Nichole <DiStefano.Nichole@epa.gov>; Brown, Tristan <Brown.Tristan@epa.gov>
Subject: RE: Urgent- HEC TSCA TA on Section 6(d)

Here is a proposed email response. Kevin has reviewed in concept but not the language.
****
We have reviewed section 6(d)(1) of the bill and current TSCA section 6(d)(2). We surmise that the issue identified by HLC is: 6(d)(1) of the bill refers to two different timing concepts (the date on which a final rule shall take effect and mandatory compliances dates), whereas section 6(d)(2) without reference to compliance dates identifies just the effective date of the final rule as the date on which the immediate effectiveness of a proposal lapses. We agree that this creates a potential issue: the effectiveness of the proposal would lapse upon the effective date of the final rule even if the compliance dates in the final rule are later than the effective date, leaving a potential gap in coverage.

To address this issue, we suggest rewording the into to 6(d)(2)(A) as follows:

"The Administrator may declare a proposed rule under subsection (a) of this section to be effective, and compliance with the proposed requirements to be mandatory, upon ~~its~~ publication in the Federal Register of the proposed rule and until the compliance dates applicable to such requirements in a final rule promulgated under section 6(a) or until the Administrator revokes such proposed rule~~effective date of final action taken~~, in accordance with subparagraph (B), ~~respecting such rule~~ if—"

Brian Grant
EPA Office of General Counsel
202-564-5503

From: Berol, David
Sent: Wednesday, May 04, 2016 12:56 PM
To: Jones, Jim <Jones.Jim@epa.gov>; Mclean, Kevin <Mclean.Kevin@epa.gov>
Cc: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Schmit, Ryan <schmit.ryan@epa.gov>; Flattery, Priscilla <Flattery.Priscilla@epa.gov>; Distefano, Nichole

<DiStefano.Nichole@epa.gov>; Grant, Brian <Grant.Brian@epa.gov>; Brown, Tristan <Brown.Tristan@epa.gov>
Subject: RE: Urgent- HEC TSCA TA on Section 6(d)

I was just about to type something up but I can be available by phone. We think we understand the perceived issue. I am running to another meeting but I am taking my phone. My work cell phone is 202-503-5992. I will step out of meeting when Jerry is available.

David Berol
U.S. EPA Office of General Counsel
202-564-6873
berol.david@epa.gov

From: Jones, Jim
Sent: Wednesday, May 04, 2016 12:51 PM
To: Mclean, Kevin <Mclean.Kevin@epa.gov>
Cc: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Schmit, Ryan <schmit.ryan@epa.gov>; Flattery, Priscilla <Flattery.Priscilla@epa.gov>; Distefano, Nichole <DiStefano.Nichole@epa.gov>; Berol, David <Berol.David@epa.gov>; Grant, Brian <Grant.Brian@epa.gov>; Brown, Tristan <Brown.Tristan@epa.gov>
Subject: Re: Urgent- HEC TSCA TA on Section 6(d)

I'd suggest OGC get in the phone with Gerry. Sven, can you arrange?

Sent from my iPhone

On May 4, 2016, at 12:49 PM, Mclean, Kevin <Mclean.Kevin@epa.gov> wrote:

> We are looking at 6(d)(2) and trying to ascertain what they could be thinking of.
>
> **From:** Kaiser, Sven-Erik
> **Sent:** Wednesday, May 04, 2016 12:26 PM
> **To:** Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Schmit, Ryan <schmit.ryan@epa.gov>; Flattery, Priscilla <Flattery.Priscilla@epa.gov>; Distefano, Nichole <DiStefano.Nichole@epa.gov>; Mclean, Kevin <Mclean.Kevin@epa.gov>; Jones, Jim <Jones.Jim@epa.gov>; Berol, David <Berol.David@epa.gov>; Grant, Brian <Grant.Brian@epa.gov>; Brown, Tristan <Brown.Tristan@epa.gov>
> **Subject:** Urgent- HEC TSCA TA on Section 6(d)
>
> TSCA team - please see urgent TA request from Jerry on section 6(d). Please let me know if any questions. Thanks,
> Sven
>
> **From:** "Couri, Jerry" <JerryCouri@mail.house.gov>
> **Date:** May 4, 2016 at 12:10:48 PM EDT
> **To:** "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
> **Cc:** "McCarthy, David" <David.McCarthy@mail.house.gov>, "Richards, Tina" <Tina.Richards@mail.house.gov>
> **Subject: Section 6(d) TA**

In talking to House Legislative Counsel, reinserting existing section 6(d)(2) could create some conflicts/overlap with new section (d)(1). Since you guys mentioned there may need to be some tweaks here, wanted to get rapid TA to clear this up and locked down.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/25/2016 4:57:19 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA leg history request - partial RE language

Michal,
This TA responds to the leg history request on partial risk evaluations. EPA suggests the following addition (in red):

Section 26(l)(4) states
"(4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.—With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6."

EPA has completed risk assessments on TCE, NMP, and MC, but has not yet proposed or finalized section 6(a) rules to address the risks that were identified. During the bicameral negotiations, EPA conveyed its concern that these risk assessments were not conducted across all conditions of use of these chemical substances, since existing TSCA does not require this to be done. EPA was concerned that if it proposed 6(a) rules to regulate these substances after TITLE was enacted, the rules could be invalidated through litigation because the risk assessments did not consider all conditions of use, and additionally noted the concern, which Congress shares, that if EPA delayed its rules for these substances in order to conduct a full risk evaluation across all conditions of use that the imposition of important public health protections that are known to be needed would also be delayed. The language House-Senate negotiators included above is intended to allow EPA to proceed with the regulation of these substances if the scope of the proposed and final rules is consistent with the scope of the risk assessments conducted on these substances (even though the risk assessments did not include a consideration of all conditions of use).

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov>
Date: May 25, 2016 at 11:29:41 AM EDT
To: "Sven-Erik Kaiser (Kaiser.Sven-Erik@epamail.epa.gov)" <Kaiser.Sven-Erik@epamail.epa.gov>
Subject: partial RE lanaguge

Section 26(l)(4) states
"(4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.—With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical

Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6."

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Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 8/26/2016 7:14:15 PM
To: Couri, Jerry [JerryCouri@mail.house.gov]
Subject: RE: EPA Establishes Science Advisory Committee on Chemicals and Seeks Experts to Serve

Jerry – the Chemicals Committee is under Jim Jones and OCSPP. The listed contact is Steven Knott of the Office of Science Coordination and Policy. OSCP is a small office under Jim's purview that coordinates science reviews for TSCA and FIFRA. Here's the org chart: https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp#oscp. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Friday, August 26, 2016 10:35 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: EPA Establishes Science Advisory Committee on Chemicals and Seeks Experts to Serve

Jim Jones signed the notice, but the contact is in ORD. What is the coordination between the two on this and who will have the final say?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, August 26, 2016 10:31 AM
Subject: EPA Establishes Science Advisory Committee on Chemicals and Seeks Experts to Serve

Today EPA published in the Federal Register a notice on the establishment of the Science Advisory Committee on Chemicals (SACC). Establishing the SACC is directed under section 26(o) of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to provide advice and recommendations on the scientific basis for risk assessments, methodologies, and pollution prevention measures or approaches.

The SACC will be composed of approximately 14 members who will serve as Special Government Employees or Regular Government Employees. SACC members will have expertise in scientific and technical fields relevant to chemical risk assessment and pollution prevention. Members will also have diverse background and experiences, including professional experiences in government, labor, public health, public interest, animal protection, industry, and other groups. EPA is seeking public comments and nominations. For more information, including how to submit comments or nominations to serve, please visit https://www.federalregister.gov/articles/2016/08/26/2016-20550/science-advisory-committee-on-chemicals-establishment-of-a-federal-advisory-committee-request-for.

The SACC expects to meet in person or by electronic means (*e.g.,* webinar) approximately 3 to 4 times a year, or as needed. The charter will be in effect for 2 years and can be renewed. A copy of the charter will be available on the EPA Web site and in the docket.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser

U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/4/2016 6:16:58 PM
To: 'Richards, Tina' [Tina.Richards@mail.house.gov]
CC: Couri, Jerry [JerryCouri@mail.house.gov]; McCarthy, David [David.McCarthy@mail.house.gov]
Subject: HEC TSCA TA request on singular/plural

Tina – this responds to the TA request below.

Sven - could you also ask Brian (think it was his comment) where there was a singular/plural issue with the data to information change -- HLC can't find it -- thanks in advance!

Here is what we understand to be the wording in the matter following 4(a)(1)(B), as modified by the 4/22 draft. The highlighted "are" should be "is".

the Administrator shall by rule, or in the case of a chemical substance described in subparagraph (A)(i), by rule or order, require that testing be conducted on such substance or mixture to develop information with respect to the health and environmental effects for which there is an insufficiency of information and experience and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of in- jury to health or the environment.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
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From: Richards, Tina [mailto:Tina.Richards@mail.house.gov]
Sent: Wednesday, May 04, 2016 1:33 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Couri, Jerry <JerryCouri@mail.house.gov>; McCarthy, David <David.McCarthy@mail.house.gov>
Subject: Re: HEC TSCA TA request Re: Section 6(d)

One last thing - could you guys give us the explanation one more time why we need the citation to the definition of chemical substance in the nomenclature savings clause? HLC doesn't want to put "section 3(2)" in and they wanted to know the explanation and none of us could exactly recall it

On May 4, 2016, at 1:07 PM, Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov> wrote:

> We think we figured it out. Cancel call request. Thanks

On May 4, 2016, at 1:01 PM, Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov> wrote:

We think it would help to do a quick call to clarify the 6(d) questions. Is 1:15pm possible? Ex. 6 - Personal Privacy code Ex. 6 - Personal Privacy Please confirm if that works. Thanks,
Sven

On May 4, 2016, at 12:39 PM, Richards, Tina <Tina.Richards@mail.house.gov> wrote:

Sven - could you also ask Brian (think it was his comment) where there was a singular/plural issue with the data to information change -- HLC can't find it -- thanks in advance!

On May 4, 2016, at 12:23 PM, Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov> wrote:

> Jerry - got it - checking. Thanks,
> Sven
>
> On May 4, 2016, at 12:10 PM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:
>
> In talking to House Legislative Counsel, reinserting existing section 6(d)(2) could create some conflicts/overlap with new section (d)(1). Since you guys mentioned there may need to be some tweaks here, wanted to get rapid TA to clear this up and locked down.
>
> Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE netwo rk.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/25/2016 3:52:37 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA Leg History - chem ID

Michal,
This responds to the legislative history TA request on chem ID. Thanks,
Sven

EPA suggested edits:

Section 14(b)(2) of the bill retains TSCA's provision making clear that information from health and safety studies is not protected from disclosure. It also retains TSCA's two existing exceptions from disclosure of information from health and safety studies: for information where disclosure would disclose either how a chemical is ~~made~~ manufactured or processed, ~~or~~ and the portion a chemical comprises in a mixture. A clarification has been added to the provision to note explicitly that the specific identity of a chemical is among the types of information that need not be disclosed, when disclosing health and safety information, if doing so would also disclose how a chemical is made or the portion a chemical comprises in a mixture. This clarification does not signal any Congressional intent to alter the meaning of the provision, only to clarify its intent.

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, May 25, 2016 10:46 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: chem ID - pls review

<!--[if !supportLists]--**1.** <!--[endif]--**Chemical Identity**

Section 14(b)(2) of the bill retains TSCA's provision making clear that information from health and safety studies is not protected from disclosure. It also retains TSCA's two existing exceptions: for information where disclosure would disclose either how a chemical is made or the portion a chemical comprises in a mixture. A clarification has been added to the provision to note explicitly that the specific identity of a chemical is among the types of information that need not be disclosed, when disclosing health and safety information, if doing so would also disclose how a chemical is made or the portion a chemical comprises in a mixture. This clarification does not signal any Congressional intent to alter the meaning of the provision, only to clarify its intent.

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations

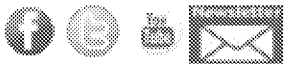
Office of Senator Edward J. Markey

255 Dirksen Senate Office Building

Washington, DC 20510

202-224-2742

Connect with Senator Markey



Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/25/2016 3:50:22 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: Sen. Markey TSCA TA Request on leg history- unreasonable risk

Michal,
This responds to the legislative history TA request on unreasonable risk. Thanks,
Sven

Suggested EPA edits. Additions in red, deletions struck out and highlighted in yellow.

<!--[if !supportLists]-->**1.** <!--[endif]-->**Unreasonable Risk**

TSCA as in effect before the date of enactment of TITLE authorized EPA to regulate chemical substances if it determined that the chemical substance "presents or will present an *unreasonable risk of injury* to health or the environment." In its decision in Corrosion Proof Fittings vs EPA[1], the U.S. Court of Appeals, 5th Circuit overturned EPA's proposed ban on asbestos, in part because it believed that

> "In evaluating what is "unreasonable," the EPA is required to consider the costs of any proposed actions and to "carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action." 15 U.S.C. § 2601(c).
>
> As the District of Columbia Circuit stated when evaluating similar language governing the Federal Hazardous Substances Act, "[t]he requirement that the risk be `unreasonable' necessarily involves a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers." *Forester v. CPSC*, 559 F.2d 774, 789 (D.C.Cir.1977). We have quoted this language approvingly when evaluating other statutes using similar language. *See, e.g., Aqua Slide*, 569 F.2d at 839."

The TITLE clearly ~~altered Congressional intent for~~ rejects that approach to determining what "unreasonable risk to health or the environment" means, by adding text that directs EPA to determine whether such risks exist "without consideration of costs or other nonrisk factors." In this manner, Congress has ~~actively sought to ensure~~ ensured that when EPA evaluates a chemical to determine whether it poses an unreasonable risk to health or the environment , it does not consider the sort of "balancing test" described above.

[1] **947 F.2d 1201 (1991)**

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Wednesday, May 25, 2016 10:26 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Distefano, Nichole <DiStefano.Nichole@epa.gov>
Subject: leg history

I'd particularly like any additional edits to this section to ensure it says everything EPA OGC feels it should. Time may be short on this generally so I will send you pieces of it as I finish them. pls turn around as quickly as you can. not clear if vote is today or tomorrow but I want to get all Senate D negotiators on this document which means I need time.

<!--[if !supportLists]-->**1.** <!--[endif]-->**Unreasonable Risk**

TSCA as in effect before the date of enactment of TITLE authorized EPA to regulate chemical substances if it determined that the chemical substance "presents or will present an *unreasonable risk of injury* to health or the environment." In its decision in Corrosion Proof Fittings vs EPA[1], the U.S. Court of Appeals, 5th Circuit overturned EPA's proposed ban on asbestos, in part because it believed that

> "In evaluating what is "unreasonable," the EPA is required to consider the costs of any proposed actions and to "carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action." 15 U.S.C. § 2601(c).
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The TITLE clearly altered Congressional intent for what "unreasonable risk to health or the environment" means, by adding text that directs EPA to determine whether such risks exist "without consideration of costs or other nonrisk factors." In this manner, Congress has actively sought to ensure that when EPA evaluates a chemical to determine whether it poses an unreasonable risk to health or the environment , it does not consider the sort of "balancing test" described above.

Michal Ilana Freedhoff, Ph.D.

---

[1] **947 F.2d 1201 (1991)**

Director of Oversight & Investigations

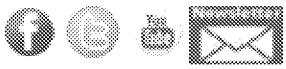
Office of Senator Edward J. Markey

255 Dirksen Senate Office Building

Washington, DC 20510

202-224-2742

Connect with Senator Markey



Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/25/2016 3:33:26 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA leg history request Re: partial RE language

Michal,
Got it, thanks,
Sven

On May 25, 2016, at 11:29 AM, Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov> wrote:

Section 26(l)(4) states
"(4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.—With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6."
EPA has completed risk assessments on TCE, NMP, and MC, but has not yet proposed or finalized section 6(a) rules to address the risks that were identified. During the bicameral negotiations, EPA conveyed its concern that these risk assessments were not conducted across all conditions of use of these chemical substances, since existing TSCA does not require this to be done. EPA was concerned that if it proposed 6(a) rules to regulate these substances after TITLE was enacted, the rules could be invalidated through litigation because the risk assessments did not consider all conditions of use, and additionally noted the concern that if EPA delayed its rules for these substances in order to conduct a full risk evaluation across all conditions of use that the imposition of important public health protections that are known to be needed would also be delayed. The language House-Senate negotiators included above is intended to allow EPA to proceed with the regulation of these substances if the scope of the proposed and final rules is consistent with the scope of the risk assessments conducted on these substances (even though the risk assessments did not include a consideration of all conditions of use).

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey
<image001.png><image002.png><image003.png><image004.jpg>

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/4/2016 6:08:17 PM
To: 'Richards, Tina' [Tina.Richards@mail.house.gov]
CC: Couri, Jerry [JerryCouri@mail.house.gov]; McCarthy, David [David.McCarthy@mail.house.gov]
Subject: RE: HEC TSCA TA request Re: Section 6(d)

Tina – this responds to the TA request on 6(d). Please let me know if any questions. Thanks,
Sven

We have reviewed section 6(d)(1) of the bill and current TSCA section 6(d)(2). We surmise that the issue identified by HLC is: 6(d)(1) of the bill refers to two different timing concepts (the date on which a final rule shall take effect and mandatory compliances dates), whereas section 6(d)(2) without reference to compliance dates identifies just the effective date of the final rule as the date on which the immediate effectiveness of a proposal lapses. We agree that this creates a potential issue: the effectiveness of the proposal would lapse upon the effective date of the final rule even if the compliance dates in the final rule are later than the effective date, leaving a potential gap in coverage.

To address this issue, we suggest rewording the into to 6(d)(2)(A) as follows:

"The Administrator may declare a proposed rule under subsection (a) of this section to be effective, and compliance with the proposed requirements to be mandatory, upon its publication in the Federal Register of the proposed rule and until the compliance dates applicable to such requirements in a final rule promulgated under section 6(a) or until the Administrator revokes such proposed rule effective date of final action taken, in accordance with subparagraph (B), respecting such rule if—"

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Richards, Tina [mailto:Tina.Richards@mail.house.gov]
Sent: Wednesday, May 04, 2016 12:40 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Couri, Jerry <JerryCouri@mail.house.gov>; McCarthy, David <David.McCarthy@mail.house.gov>
Subject: Re: HEC TSCA TA request Re: Section 6(d)

Sven - could you also ask Brian (think it was his comment) where there was a singular/plural issue with the data to information change -- HLC can't find it -- thanks in advance!

On May 4, 2016, at 12:23 PM, Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov> wrote:

> Jerry - got it - checking. Thanks,

Sven

On May 4, 2016, at 12:10 PM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:

In talking to House Legislative Counsel, reinserting existing section 6(d)(2) could create some conflicts/overlap with new section (d)(1). Since you guys mentioned there may need to be some tweaks here, wanted to get rapid TA to clear this up and locked down.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/4/2016 4:48:46 PM
To: Richards, Tina [Tina.Richards@mail.house.gov]
CC: Couri, Jerry [JerryCouri@mail.house.gov]; McCarthy, David [David.McCarthy@mail.house.gov]
Subject: Re: HEC TSCA TA request Re: Section 6(d)

Tina- got it. Thanks,
Sven

On May 4, 2016, at 12:39 PM, Richards, Tina <Tina.Richards@mail.house.gov> wrote:

Sven - could you also ask Brian (think it was his comment) where there was a singular/plural issue with the data to information change -- HLC can't find it -- thanks in advance!

On May 4, 2016, at 12:23 PM, Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov> wrote:

> Jerry - got it - checking. Thanks,
> Sven
>
> On May 4, 2016, at 12:10 PM, Couri, Jerry <JerryCouri@mail.house.gov> wrote:
>
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Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/4/2016 4:00:32 PM
To: 'McCarthy, David' [David.McCarthy@mail.house.gov]
CC: Cohen, Jacqueline [jackie.cohen@mail.house.gov]
Subject: HEC TSCA TA questions - confidential please

Dave,
Thanks for the TA request. We will take these questions in hand when looking at the new confidential draft. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: McCarthy, David [mailto:David.McCarthy@mail.house.gov]
Sent: Wednesday, May 04, 2016 11:58 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Cohen, Jacqueline <jackie.cohen@mail.house.gov>
Subject: confidential please

Dear Sven

Thanks for chatting just now. Later today, we expect to receive a new draft that incorporates changes to the April 22 draft we've discussed over the last couple days. When we send it to you, we think we will be asking questions such as the following: Just want to confirm with you that, as you see it whole, you think it's language that you can implement. In particular, will you know how to administer Section 5 as drafted? Does it clearly provide that an affirmative action by EPA is needed before a manufacturer may begin manufacturing? Is that decision risk-based? ? In Section 6 will EPA be able to implement the prioritization provision? Are EPA's choices clear at the end of the prioritization phase? In Section 26, do you understand what your discretion and limitations are in setting, collecting, and using user fees? As you guys know pretty much what to expect based on your extraordinary help yesterday, just wanted to give you a head-start thinking through these questions. Thanks to you, we are confident that there are no implementation stumbling blocks in the bill. I don't recall significant changes from April 22 to the sections we did not work on yesterday.
Thanks ever so much. Dave

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 5/2/2016 9:36:20 PM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]
Subject: HEC TSCA TA Request on section 5(e) and 5(f)- followup

Jerry,
This responds to the followup question on reg and statutory citations.

Is 7 USC 136d(c) the statutory underpinning for 40 CFR Part 164?

EPA: yes

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Monday, May 02, 2016 5:29 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: HEC TSCA TA Request on section 5(e) and 5(f)

Thanks. Is 7 USC 136d(c) the statutory underpinning for 40 CFR Part 164?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, May 02, 2016 5:09 PM
To: Couri, Jerry; Cohen, Jacqueline; McCarthy, David; Richards, Tina
Subject: HEC TSCA TA Request on section 5(e) and 5(f)

Jerry,
This TA responds to the request on section 5(e) and 5(f).

1. What forms of appeal, such as TSCA section 19 judicial review or other Federal law, exist for orders issued under newly proposed TSCA section 5?

An EPA order under 5(e) or 5(f) would be a final agency action subject to judicial review. As the bill currently stands, judicial review of these orders would be in U.S. District Court, subject to a 6 year statute of limitations, under the Administrative Procedure Act. There is no need for the bill to specifically incorporate these terms of review as they already apply, by default.

Section 19 could be revised to provide for an alternative judicial review process for 5(e) and 5(f) orders. For example, these orders could be added to the list of actions that are reviewed in the Courts of Appeals, subject to a 60 day filing deadline.

2. Are there existing administrative appeal provisions in FIFRA – or other EPA administered laws -- regarding orders (or rules in the case of 5(f)(2)) that could be used in place of existing subsections (e)(1)(C), (e)(2), and most of (f)(3)?

The organization in EPA that handles most administrative appeals is the Environmental Appeals Board, which stands in for the Administrator for such purposes. EPA regulations at 40 CFR 124.19 set forth the procedure for appealing various Agency orders under RCRA, the Safe Drinking Water Act, the Clean Water Act, and the Clean Air Act. EPA regulations at 40 CFR Part 164 similarly provide for appealing the outcome of a FIFRA hearing to the Environmental Appeals Board.

If the drafters wished to establish an administrative appeals process, the mechanism for doing so would be to provide that proposed 5(e) and 5(f) orders are issued by the "Assistant Administrator for Toxic Substances of the Environmental Protection Agency" (defined in 26(g)), and that "appeals as a matter of right shall lie to the Administrator or such Appeals Board as the Administrator may designate." The reason for having two different levels of decision making would be to be clear that the Administrator is not reviewing the appeal of a decision she has herself just made.

Note that a consequence of establishing an opportunity for administrative appeal of a 5(e) or 5(f) order is that manufacturers would need to go through the administrative appeal process before seeking judicial review of the Agency's final decision. This is due to the doctrine of "administrative exhaustion," whereby courts won't accept review of Agency decisions until the available administrative appeals processes have played themselves out.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Monday, May 02, 2016 1:46 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Cohen, Jacqueline <jackie.cohen@mail.house.gov>; McCarthy, David <David.McCarthy@mail.house.gov>; Richards, Tina <Tina.Richards@mail.house.gov>
Subject: TA Request

Sven:

In response to the TA the Agency provided to the Committee on subsections (e) and (f) TSCA section 5 (15 USC 2604), we would like further TA on two separate questions relating to the suggested strikes of subsections (e)(1)(C), (e)(2), and most of (f)(3) .

1. What forms of appeal, such as TSCA section 19 judicial review or other Federal law, exist for orders issued under newly proposed TSCA section 5?
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Thanks.

■ Jerry

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)

Message

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Sent: 5/2/2016 9:31:15 PM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]
Subject: RE: HEC TSCA TA Request on section 5(e) and 5(f)

Jerry, got it, checking. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
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1200 Pennsylvania Ave., NW (1305A)
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Sent: Monday, May 02, 2016 5:29 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: HEC TSCA TA Request on section 5(e) and 5(f)

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Sven

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Subject: TA Request

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Thanks.

- Jerry

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 12/17/2015 7:35:16 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey TSCA TA Requests

thanks

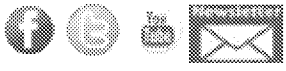
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 17, 2015 2:25 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Requests

At present, Tues of next week would be fine. If that changes, I will let you know. Do whichever is fastest for you to do first.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, December 17, 2015 2:23 PM
To: Freedhoff, Michal (Markey)
Subject: RE: Sen. Markey TSCA TA Requests

Michal - It might take until Tues of next week and then it gets harder as people start taking holiday leave.
Thanks,
Sven

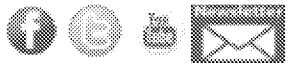
Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 17, 2015 1:52 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey TSCA TA Requests

Yes, I'd like both, and my guess on timing on next steps is as good as anyone's today. What is your sense of how long each would take?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, December 17, 2015 1:51 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey TSCA TA Requests

Michal – what's your sense of timing on the multipart TA request. Also, do you still want the TA on the 4 different ways to factor costs, and if so, do you want that before or after the multipart request below. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, December 17, 2015 12:31 PM
To: Distefano, Nichole <DiStefano.Nichole@epa.gov>
Subject: TA request

Hi Nichole

I was hoping to get responses to the following questions:

1) The safety standard approach in this bill uses underlying TSCA's "unreasonable risk" lexicon. In the changes to TSCA section 6, EPA is told not to include costs or other non-risk factors, which presumably allows EPA to make chemical safety decisions exclusively using scientific risk assessments. Do you agree with my assessment of this as far as Section 6 goes? Does EPA also believe that this bill ensures that EPA cannot consider costs or other non-risk factors in other sections of TSCA, and if not, why not?

Does this bill address in totality throughout TSCA the "unreasonable risk" argument that was used to overturn the asbestos ban?

2) Does EPA have the authority it needs under this bill to require testing of chemicals? Is the current TSCA catch-22 test finding which requires EPA to find that there may be an unreasonable risk BEFORE requiring such testing removed in this language?
3) Does EPA have sufficient flexibility in this bill to appropriately consider costs of rulemaking, while also ensuring that it will not have undue litigation risk or incur analytic burden if it does not find that a cost-effective regulatory option that will address the risk the chemical poses exists?
4) Is EPA required to assess the safety of a new chemical on vulnerable subpopulations under this bill?
5) Does this text give EPA the clear authority to set priorities for conducting risk evaluations that allows EPA to study chemicals that are ubiquitous OR known/suspected hazards? Are there deadlines that are enforceable for EPA to conduct its chemical safety responsibilities in this bill?
6) Does this bill require manufacturers to substantiate new and old CBI claims? Can data relevant to health and safety be treated as CBI under this bill? Does EPA have authority under this bill to provide CBI to state and local governments when necessary?
7) Does this bill ensure that EPA will get sufficient industry and other resources to fund its TSCA activities? How does this bill's funding for EPA intersect with the ability for industry to request that EPA perform risk evaluations under the bill?
8) Does the bill give EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals?

Thanks
Michal

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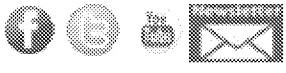

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 12/16/2015 10:34:46 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on Unreasonable Risk

Michal,
This responds to your technical assistance request on "unreasonable risk." Please let me know if any questions. Thanks,
Sven

Question: If the section 4 test finding catch 22 was removed or changed to something like "basis for concern" or something like that, under House text, would EPA be able to request some data from industry on a chemical that was ubiquitous but about which little was known in order to establish some potential for hazard (and then be able to proceed with a risk evaluation)? I don't think I read the House bill as allowing this, I think I read it as allowing testing once a risk evaluation is already underway. But if so, would EPA be likely to use its section 4 authority and resources that way, or would it be more likely to use it on substances for which the "may pose an unreasonable risk" section 6 finding could more easily be made?

EPA Response: TSCA section 4 provides two bases for requiring testing: a finding the a chemical substance may present unreasonable risk (4(a)(1)(A)), and a finding based on production volume, release and/or exposure (4(a)(1)(B)). You previously asked whether the section 4 findings could be made for ubiquitous chemicals, and our answer was that they likely could under (B), but only for chemicals manufactured at substantial volumes. We understand that you now want to know if a change to the (A) findings would provide another, perhaps more certain, basis to require testing for ubiquitous chemicals.

We think it would, if by "ubiquitous" you mean a chemical with widespread exposure. If the (A) finding were changed to require only a showing that EPA has a basis for concern, we believe that language – plus the fact that Congress intentionally moved away from the "may present" standard – would give EPA a good basis to require testing of such a chemical in the absence of information demonstrating that the chemical posed little or no hazard. EPA would still need to show that there are insufficient data and experience as to the chemical to enable the Agency to determine or predict the effects of the chemical, and that testing is necessary to close the data gaps – findings that EPA must make under both (A) and (B) (4(a)(1)(A)(ii) and (iii), 4(a)(1)(B)(ii) and (iii)). But, again, for a chemical with widespread exposure, we think EPA would most likely be able to demonstrate a basis for concern so long as the Agency could show that there were open questions about hazard.

You also suggest the possibility of simply dropping the "may present" standard, rather than replacing it. We don't think that would make sense, since the (A) basis for testing would have no function if it contained no standard.

Finally, you asked whether or not EPA would be likely to use section 4, if given the authority, to help clear the hurdle to initiating a risk evaluation under section 6 of the House bill. We would not want to rule out this use of section 4 authority, but think such use would be fairly minimal, particularly in the earlier years of implementation when the focus would be on TSCA Work Plan chemicals and other chemicals that for which there is some information. EPA would interpret the bar for initiating a risk evaluation on non-Work Plan chemicals under 6(b)(3)(A)(i) as fairly low. The House language requires that EPA make a finding that the chemical substance "may present an unreasonable risk," but that finding is based on potential hazard and a potential route of exposure. We interpret this as not requiring actual or documented hazard/exposure information. And because we don't anticipate the 6(b)(3)(A)(i) finding to be a significant barrier to initiating risk evaluations, we also don't anticipate a regular need to invoke section 4 testing authority to overcome it. A

more likely use of section 4 would be to support necessary analysis during the risk evaluation, and ultimately, a determination of whether or not the chemical substance "presents or will present…an unreasonable risk."

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Sunday, December 06, 2015 9:53 AM
To: Distefano, Nichole <DiStefano.Nichole@epa.gov>
Cc: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>; Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>
Subject: TA request (for starting on Monday)

Nichole

We've very much appreciated the rapid turn around on questions related to the "may pose an unreasonable risk" section 4 and 6 text of House/TSCA, as well as efforts to understand what it could mean for EPA to have to determine both potential exposure and potential hazard under section 6 before starting a risk evaluation.

I'm trying to understand whether the solution on section 6 could be in section 4.

If the section 4 test finding catch 22 was removed or changed to something like "basis for concern" or something like that, under House text, would EPA be able to request some data from industry on a chemical that was ubiquitous but about which little was known in order to establish some potential for hazard (and then be able to proceed with a risk evaluation)? I don't think I read the House bill as allowing this, I think I read it as allowing testing once a risk evaluation is already underway. But if so, would EPA be likely to use its section 4 authority and resources that way, or would it be more likely to use it on substances for which the "may pose an unreasonable risk" section 6 finding could more easily be made?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 12/16/2015 3:34:25 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey TSCA TA Request on RE: TA request
Attachments: Markey.TSCA TA.Pace of Risk Evaluations.docx

Michal,
This responds to your technical assistance request related to ensuring the pace of risk evaluations. Please see the attached redline version and let me know if any additional questions.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and comments. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, December 15, 2015 11:01 AM
To: Distefano, Nichole <DiStefano.Nichole@epa.gov>
Subject: TA request

Hi Nichole

Can you possibly suggest some ways, drafted to House text, that would ensure that the House pace of 10 risk evaluations/year would be assured?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
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255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

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(b) Risk Evaluations.--Section 6(b) of the Toxic Substances Control Act (15 U.S.C. 2605(b)) is amended to read as follows:

``(b) Risk Evaluations.--

``(1) In general.--The Administrator shall conduct risk evaluations pursuant to this subsection to determine whether or not a chemical substance presents or will present, in the absence of requirements under subsection (a), an unreasonable risk of injury to health or the environment.

``(2) Applying requirements.--The Administrator shall apply requirements with respect to a chemical substance through a rule under subsection (a) only if the Administrator determines through a risk evaluation under this subsection, without consideration of costs or other non-risk factors, that the chemical substance presents or will present, in the absence of such requirements, an unreasonable risk of injury to health or the environment.

``(3) Conducting risk evaluation.--

``(A) Required risk evaluations.--The Administrator shall conduct and publish the results of a risk evaluation under this subsection for a chemical substance if--

``(i) the Administrator determines that the chemical substance may present an unreasonable risk of injury to health or the environment because of potential hazard and a potential route of exposure under the intended conditions of use; or

``(ii) a manufacturer of the chemical substance requests such a risk evaluation in a form and manner prescribed by the Administrator.

``(B) TSCA work plan chemicals.--The Administrator may, without making a determination under subparagraph (A)(i), conduct and publish the results of a risk evaluation under this subsection for a chemical substance that, on the date of enactment of the TSCA Modernization Act of 2015, is listed in the TSCA Work Plan for Chemical Assessments published by the Administrator.

``(4) Requirements.--In conducting a risk evaluation under this subsection, the Administrator shall--

``(A) integrate and assess information on hazards and exposures for all of the intended conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed subpopulations;

``(B) not consider information on cost and other factors not directly related to health or the environment;

``(C) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the intended conditions of use of the chemical substance;

``(D) describe the weight of the scientific evidence for identified hazard and exposure;

``(E) consider whether the weight of the scientific evidence supports the identification of doses of the chemical substance below which no adverse effects can be expected to occur; and

``(F) in the case of a risk evaluation requested by a manufacturer under paragraph (3)(A)(ii), ensure that the costs to the Environmental Protection Agency,

including contractor costs, of conducting the risk evaluation are paid for by the manufacturer.

``(5) Deadlines.--

``(A) Risk evaluations.--The Administrator shall conduct and publish a risk evaluation under this subsection for a chemical substance as soon as reasonably possible, subject to the availability of resources, but not later than--

``(i) 3 years after the date on which the Administrator--

``(I) makes a determination under paragraph (3)(A)(i); or

``(II) begins the risk evaluation under paragraph (3)(B); or

``(ii) in the case of a risk evaluation requested by a manufacturer under paragraph (3)(A)(ii), 2 years after the later of the date on which--

``(I) the manufacturer requests the risk evaluation; or

``(II) if applicable, the risk evaluation is initiated pursuant to subparagraph (B).

``(B) Deadline adjustment.--If the Administrator receives ~~more requests for risk evaluations under paragraph (3)(A)(ii) than the Administrator has resources to pursue by the deadline under paragraph (5)(A)(i), taking into account the requirements of paragraph (4)(A)(ii),~~ requests for risk evaluations under paragraph (3)(A)(ii) that would, if granted, cause the number of ongoing risk evaluations under paragraph (3)(A)(ii) to exceed [X] percent of the total number of ongoing risk evaluations, then the Administrator ~~shall~~--

Commented [A1]: This protection doesn't clearly kick in until the demands of completing industry-initiated risk evaluations have matched EPA's total processing capacity. If the objective is to ensure a certain proportionality between the chemicals being reviewed on EPA's initiative and those being reviewed on industry initiative, that should be addressed more directly.

``(i) shall not accept any such requests for risk evaluations under paragraph (5)(A)(ii) until a sufficient number of risk evaluations under (2)(A)(i) or (5)(B) have been initiated to ensure that the specified percentage of risk evaluations under (2)(A)(ii) is not exceeded ~~that exceed the Administrator's allotted resources to soon as resources for such risk evaluations are available~~; and

``(ii) shall not collect a fee under section 26 from the manufacturer for a risk evaluation under (3)(A)(ii) until the Administrator initiates the risk evaluation.

``(C) Subsection (a) rules.--If, based on a risk evaluation conducted under this subsection, the Administrator determines, without consideration of costs or other non-risk factors, that a chemical substance presents or will present, in the absence of a rule under subsection (a), an unreasonable risk of injury to health or the environment, the Administrator shall--

``(i) propose a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the risk evaluation regarding such chemical substance is published under subparagraph (A); and

``(ii) publish in the Federal Register a final rule not later than 2 years after the date on which the risk evaluation regarding such chemical substance is published under subparagraph (A).

``(D) Extension.--If the Administrator determines that additional information is necessary to make a risk evaluation determination under this subsection, the

Administrator may extend the deadline under subparagraph (A) accordingly, except that the deadline may not be extended to a date that is later than--

``(i) 90 days after receipt of such additional information; or

``(ii) 2 years after the deadline being extended under this subparagraph.

``(6) Determinations of no unreasonable risk.--

``(A) Notice and comment.--Not later than 30 days before publishing a final determination under this subsection that a chemical substance does not and will not present an unreasonable risk of injury to health or the environment, the Administrator shall make a preliminary determination to such effect and provide public notice of, and an opportunity for comment regarding, such preliminary determination.

``(B) Potentially exposed subpopulations.--The Administrator shall not make a determination under this subsection that a chemical substance will not present an unreasonable risk of injury to health or the environment if the Administrator determines that the chemical substance, under the intended conditions of use, presents or will present an unreasonable risk of injury to one or more potentially exposed subpopulations.

``(C) Final action.--A final determination under this subsection that a chemical substance will not present an unreasonable risk of injury to health or the environment shall be considered a final agency action.

``(7) Minimum number.--Subject to the availability of appropriations, the Administrator shall initiate 10 or more risk evaluations under paragraphs (3)(A)(i) or (3)(B) in each

fiscal year beginning in the fiscal year of the date of enactment of the TSCA Modernization Act of 2015.''.

*****

SEC. 8. ADMINISTRATION OF THE ACT.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended--

(1) in subsection (b)(1)--

(A) by striking ``of a reasonable fee'';

(B) by inserting ``of a fee that is sufficient and not more than reasonably necessary'' after ``section 4 or 5'';

(C) by inserting ``, or who requests a risk evaluation under section 6(b)(3)(A)(ii),'' before ``to defray the cost'';

(D) by striking ``this Act'' and inserting ``the provision of this title for which such fee is collected'';~~and~~

(E) by inserting after the text added by (D) "In the case of a fee collected from a person who requests a risk evaluation under section 6(b)(3)(A)(ii), in addition to defraying the cost of administering that provision, the fee shall also be sufficient and not more than necessary to carry out obligations under 6(b)(5)(C) resulting from the Administrator's completion of the risk [illegible]."; and

(F) by striking ``Such rules shall not provide for any fee in excess of $2,500 or, in the case of a small business concern, any fee in excess of $100.'' and inserting ``Such rules shall provide for lower fees for small business concerns.'';

(2) by adding at the end of subsection (b) the following:

Commented [A2]: To ensure that industry funds risk management arising from industry requests, in addition to the evaluations, to avoid swallowing Agency resources for other priorities

``(3) Fund.--

``(A) Establishment.--There is established in the Treasury of the United States a revolving fund, to be known as the TSCA Service Fee Fund (in this paragraph referred to as the `Fund'), consisting of such amounts as are deposited in the Fund under this paragraph.

``(B) Collection and deposit of fees.--The Administrator shall collect the fees described in paragraph (1) and deposit those fees in the Fund.

``(C) Crediting and availability of fees.--On request by the Administrator, the Secretary of the Treasury shall transfer from the Fund to the Administrator amounts appropriated to pay or recover the full costs incurred by the Environmental Protection Agency, including contractor costs, in carrying out the provisions of this title for which the fees are collected under paragraph (1), and in carrying out obligations under 6(b)(5)(C) resulting from the Administrator's completion of a risk evaluation that was requested under section 6(b)(4)(A)(ii).

``(D) Use of funds by administrator.--Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation for use only in administering the provisions of this title for which the fees are collected.

``(E) Accounting and auditing.--

``(i) Accounting.--The Administrator shall biennially prepare and submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes an accounting of the fees paid to the Administrator under this paragraph and amounts disbursed from the Fund for the period

covered by the report, as reflected by financial statements provided in accordance with sections 3515 and 3521 of title 31, United States Code.

``(ii) Auditing.--

``(I) In general.--For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of a covered executive agency.

``(II) Components of audit.--The annual audit required in accordance with sections 3515 and 3521 of title 31, United States Code, of the financial statements of activities carried out using amounts from the Fund shall include an analysis of--

``(aa) the fees collected and amounts disbursed under this subsection;

``(bb) the reasonableness of the fees in place as of the date of the audit to meet current and projected costs of administering the provisions of the title for which the fees are collected; and

``(cc) the number of requests for a risk evaluation made by manufacturers under section 6(b)(3)(A)(ii).

``(III) Federal responsibility.--The Inspector General of the Environmental Protection Agency shall conduct the annual audit described in subclause (II) and submit to the Administrator a report that describes the findings and any recommendations of the

Inspector General resulting from the audit.'';

and

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 12/16/2015 3:31:45 PM
To: 'Fruci, Jean' [Jean.Fruci@mail.house.gov]; Kessler, Rick [Rick.Kessler@mail.house.gov]; Wright, Tuley [Tuley.Wright@mail.house.gov]
Subject: HEC min TSCA TA Request on Pace of Risk Evaluations
Attachments: HEC min.TSCA TA.Pace of Risk Evaluations.docx

Jean,
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Sven

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``(D) describe the weight of the scientific evidence for identified hazard and exposure;

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including contractor costs, of conducting the risk evaluation are paid for by the manufacturer.

``(5) Deadlines.--

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``(ii) publish in the Federal Register a final rule not later than 2 years after the date on which the risk evaluation regarding such chemical substance is published under subparagraph (A).

``(D) Extension.--If the Administrator determines that additional information is necessary to make a risk evaluation determination under this subsection, the

Administrator may extend the deadline under subparagraph (A) accordingly, except that the deadline may not be extended to a date that is later than--

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(D) by striking ``this Act'' and inserting ``the provision of this title for which such fee is collected'';~~and~~

E) by inserting after the text added by (D) "In the case of a fee collected from a person who requests a risk evaluation under section 6(b)(3)(A)(ii), in addition to defraying the cost of administering that provision, the fee shall also be sufficient and not more than necessary to carry out obligations under 6(b)(5)(C) resulting from the Administrator's completion of the risk evaluation."; and

(F) by striking ``Such rules shall not provide for any fee in excess of $2,500 or, in the case of a small business concern, any fee in excess of $100.'' and inserting ``Such rules shall provide for lower fees for small business concerns.'';

(2) by adding at the end of subsection (b) the following:

Commented [A2]: To ensure that industry funds risk management arising from industry requests, in addition to the evaluations, to avoid swallowing Agency resources for other priorities

``(3) Fund.--

``(A) Establishment.--There is established in the Treasury of the United States a revolving fund, to be known as the TSCA Service Fee Fund (in this paragraph referred to as the `Fund'), consisting of such amounts as are deposited in the Fund under this paragraph.

``(B) Collection and deposit of fees.--The Administrator shall collect the fees described in paragraph (1) and deposit those fees in the Fund.

``(C) Crediting and availability of fees.--On request by the Administrator, the Secretary of the Treasury shall transfer from the Fund to the Administrator amounts appropriated to pay or recover the full costs incurred by the Environmental Protection Agency, including contractor costs, in carrying out the provisions of this title for which the fees are collected under paragraph (1), and in carrying out obligations under 6(b)(5)(C) resulting from the Administrator's completion of a risk evaluation that was requested under section 6(b)(3)(A)(ii).

``(D) Use of funds by administrator.--Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation for use only in administering the provisions of this title for which the fees are collected.

``(E) Accounting and auditing.--

``(i) Accounting.--The Administrator shall biennially prepare and submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes an accounting of the fees paid to the Administrator under this paragraph and amounts disbursed from the Fund for the period

covered by the report, as reflected by financial statements provided in accordance with sections 3515 and 3521 of title 31, United States Code.

``(ii) Auditing.--

``(I) In general.--For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of a covered executive agency.

``(II) Components of audit.--The annual audit required in accordance with sections 3515 and 3521 of title 31, United States Code, of the financial statements of activities carried out using amounts from the Fund shall include an analysis of--

``(aa) the fees collected and amounts disbursed under this subsection;

``(bb) the reasonableness of the fees in place as of the date of the audit to meet current and projected costs of administering the provisions of the title for which the fees are collected; and

``(cc) the number of requests for a risk evaluation made by manufacturers under section 6(b)(3)(A)(ii).

``(III) Federal responsibility.--The Inspector General of the Environmental Protection Agency shall conduct the annual audit described in subclause (II) and submit to the Administrator a report that describes the findings and any recommendations of the

Inspector General resulting from the audit.'';

and

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 1/21/2016 12:12:46 AM
To: 'kenneth.degraff@mail.house.gov' [kenneth.degraff@mail.house.gov]
Subject: Administration Views on TSCA Reform Bills
Attachments: TSCA Reform Views.Pallone.pdf

Kenneth,
Please see attached and let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

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Sent: 7/30/2015 6:14:09 PM
To: Zipkin, Adam (Booker) [Adam_Zipkin@booker.senate.gov]; Levine, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=468b48e304cf4c54a52bb7c83a54fd21-CLevin02]
Subject: Sen. Booker inquiry on Tull Chemical

Adam,
Thanks for the request. I'm looping in my colleague Carolyn Levine to assist. Please let me know if any additional questions. Best,
Sven

On Jul 30, 2015, at 1:18 PM, "Zipkin, Adam (Booker)" <Adam_Zipkin@booker.senate.gov> wrote:

Hello Sven!

This is a link to an article referring to safety problems identified by EPA at the Tull factory: http://jacksonville.com/tu-online/apnews/stories/121304/D86UI3MG1.shtml "Lea Cheatwood has lived about 150 yards from Tull Chemical for decades, but she didn't know what the company made until the early '90s, when a neighbor obtained a copy of an EPA audit that cited numerous safety problems at the small plant, located about 50 miles east of Birmingham."

Could Senator Booker be provided copies of any EPA audits of the Tull facility?

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Sent: Monday, July 27, 2015 7:59 AM
To: Zipkin, Adam (Booker) <Adam_Zipkin@booker.senate.gov>
Subject: Re: Sen. Booker TSCA TA Request on Compound 1080

Checking on availability. Thanks,
Sven

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Thanks! Adam

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Adam,
David can do a call Monday anytime before 2 pm. Can you give me an idea of your questions so I get the right folks on the line. Thanks,
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On Jul 24, 2015, at 4:20 PM, "Zipkin, Adam (Booker)" <Adam_Zipkin@booker.senate.gov> wrote:

Sven – I had a few follow up questions -- might it be possible to talk with David again on Monday?

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Sent: Thursday, July 23, 2015 10:27 AM
To: Zipkin, Adam (Booker) <Adam_Zipkin@booker.senate.gov>
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Great – please call 866-299-3188, code 202-566-2753 at 4:30 pm. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

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Adam,
Available today for a call 10-11:30 and after 3pm. Thanks,
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On further reflection here, if you want to discuss further about the relationship between TSCA and FIFRA, I can offer a call with one of our attorneys who handles both statutes (sort of like speaking two languages). Thanks,
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From: Kaiser, Sven-Erik
Sent: Monday, July 20, 2015 9:15 AM
To: 'Zipkin, Adam (Booker)'
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Adam,
FIFRA includes pests – defined as living organisms that occur where they are not wanted or that cause damage to crops or humans or other animals. Examples include:

- <!--[if !supportLists]--><!--[endif]-->insects,
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Please let me know if you would like a call with FIFRA folks on sodium fluoroacetate. Thanks,
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To: Kaiser, Sven-Erik
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Thanks Sven -- that is helpful, as I am still learning. Please see attached article which states "Sodium Fluoroacetate, also highly toxic, is a "restricted use" chemical, that is only approved for use to protect livestock from coyotes and can only be used by a licensed professional" – so that approved use (protecting livestock from coyotes) is pursuant to FIFRA? When I think of pesticides, I tend to think of chemicals used to kill bugs, not coyotes -- but sounds like definition of "pest" may be broader than I thought and include animals such as coyotes?

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Please clarify whether you are inquiring about a TSCA ban of the non-pesticidal uses of sodium fluoroacetate, or about a TSCA ban of the pesticidal uses of sodium fluoroacetate. (The latter would require altering the TSCA definition of "chemical substance"). This clarification will help us to scope our response accordingly.

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Sent: 7/30/2015 5:28:21 PM
To: Zipkin, Adam (Booker) [Adam_Zipkin@booker.senate.gov]
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Adam,
Got it, checking. Thanks,
Sven

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Sent: 6/7/2016 9:22:19 PM
To: 'Albritton, Jason (EPW)' [Jason_Albritton@epw.senate.gov]; Poirier, Bettina (EPW) [Bettina_Poirier@epw.senate.gov]; Distefano, Nichole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31d32a3a3a9e4591b5fdfc3eb96e8b78-Distefano,]; 'Deveny, Adrian (Merkley)' [Adrian_Deveny@merkley.senate.gov]; 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: TSCA TA Request on Scientific Standards in Statement for the Record

Jason,
This TA responds to the requests on scientific standards language in the draft Statement for the Record. EPA reviewed the language and believes that your revised language with additional changes best addresses the issue.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Albritton, Jason (EPW) [mailto:Jason_Albritton@epw.senate.gov]
Sent: Tuesday, June 07, 2016 4:08 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Distefano, Nichole <DiStefano.Nichole@epa.gov>; Poirier, Bettina (EPW) <Bettina_Poirier@epw.senate.gov>
Subject: TA

All,

We understand you are reviewing language from Merkley's office on scientific standards. We just suggested these additional changes below to this language. So, we wanted to make sure to get your feedback on our suggested changes as well. Please let us know if you have any comments ASAP.

Jason

Scientific Standards

Section 26(h) incorporates a number of principles of good scientific practice and directs EPA to "consider" these principles "as applicable." These principles are now reflected in the various guidelines and policies that EPA uses to review data and conduct risk evaluations and it is not expected that these guidelines and policies will need to be revised. In general, EPA retains broad scientific judgment to determine how to weigh the data and other information it considers in evaluating chemical risks and addressing issues of hazard and exposure that bear on determinations of unreasonable risk. Section 26(h) reinforces EPA's obligation to document its

assumptions and judgments and explain the basis for its risk determinations consistent with good sciences principles but is not intended to micromanage or second-guess EPA's evaluations of risk.

Section 28(i) directs EPA to base decisions on the 'weight of the scientific evidence." The term ''weight of evidence'' refers to a systematic review method that ~~uses a pre-established protocol to~~ comprehensively, objectively, transparently, and consistently, identifies and evaluates each stream of evidence, including strengths, limitations, and relevance of each study and ~~to~~ that integrates evidence as necessary and appropriate to characterize hazards, exposures and risks based upon strengths, limitations, and relevance. This requirement is not intended to prevent the Agency from considering academic studies, or any other category of study that may provide relevant information. Nor is it intended to narrow EPA's scientific judgment in determining how much weight to place on different pieces of evidence. ~~We expect that when EPA makes a weight of the evidence decision it will fully describe its use and methods.~~

Jason Albritton
Senior Policy Advisor
Senate Committee on Environment and Public Works
Senator Barbara Boxer, Ranking Member
456 Dirksen Senate Office Building

Tel: 202-224-8832
Fax: 202-224-1273

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/7/2016 9:13:27 PM
To: 'Deveny, Adrian (Merkley)' [Adrian_Deveny@merkley.senate.gov]
Subject: Sen. Merkley TSCA TA Request on the Statement for the Record - Industry Requested Chemicals

Adrian,
This TA responds to the request on the industry requested chemicals language for the Statement for the Record. EPA reviewed the draft language on industry requested chemicals and has no comments. We will respond to the TA request on scientific standards in a separate note.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions. Thanks,
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Washington, DC 20460
202-566-2753

From: Deveny, Adrian (Merkley) [mailto:Adrian_Deveny@merkley.senate.gov]
Sent: Tuesday, June 07, 2016 2:02 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: statment for the record

Hi Sven
Can you run the traps on this language for the stmt for the record?

Scientific Standards
The term ''weight of evidence'' refers to a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance. This requirement is not intended to prevent the Agency from considering academic studies, or any other category of study. We expect that when EPA makes a weight of the evidence decision it will fully describe its use and methods.

Industry Requested Chemicals
Sec. 6(b)(4)(E) sets the percentage of risk evaluations that the Administrator shall conduct at industry's request at between 25 percent (if enough requests are submitted) and 50 percent. The Administrator should set up a system to ensure that those percentages are met and not exceeded in each fiscal year. An informal effort that simply takes requests as they come in and hopes that the percentages will work out does not meet the requirement that the Administrator "ensure" that the percentages be met. Also, clause (E)(ii) makes clear that industry requests for risk evaluations "shall be" subject to fees. Therefore, if at any point the fees imposed by the Frank Lautenberg Act (which are subject to a termination in section 26(b)(6)) are allowed to lapse, industry's opportunity to seek risk evaluations will also lapse and the minimum 25 percent requirement will not apply.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 8/17/2016 9:12:09 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey Inquiry on PCBs
Attachments: Markey.PCB.Set 1.docx

Michal – attached is the first of responses to the dozen PCB questions including #1,3,5,6,7, and 11. The rest are in production and I'll send as soon as available. Also I'm working on setting up a call on question 9 (Asbestos Trust Fund). Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, July 19, 2016 5:59 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Bogdanoff, Alec (Markey) <Alec_Bogdanoff@markey.senate.gov>
Subject: PCB questions

Sven

Here are a bunch of questions for your team – thanks. It would be great to get your sense of how long these will take to respond to. It is fine with me if you respond to them as you get each one answered - no need to wait til they are all done if you think some will take longer than others. I've attached our MASK Act, which I know you've looked at before, for your reference.

Thanks
michal

1. Do contractors that are remediating PCB-containing building materials like those that might be found in schools require special accreditation the way asbestos-workers do? if not, should they, or is the removal of such materials less complicated to do? what about inspectors? Title II of TSCA goes on at some length about the types of courses and certifications that are required by asbestos contractors and inspectors – is something like this needed (or is it already in the 6e rules) for PCBS?

2. Title II of TSCA defines ASBESTOS-CONTAINING MATERIAL.—The term ''asbestos- containing material'' means any material which contains more than 1 percent asbestos by weight. I know you are in the midst of re-drafting your PCB rules. Would a definition of PCB-CONTAINING MATERIAL which I drew from your 1998 PCB regulation make sense, or are there different/more items I should be considering?

"The term polychlorinated biphenyl-containing material means 1) a fluorescent light ballast that contains more than 50 parts per million in the insulating material which fills the space between the functioning parts of the ballast and its outer metal covering, 2) a nonliquid material containing polychlorinated biphenyls at concentrations of more than 50 parts per million but less than 500 parts per million [QUESTION – WOULD THIS CAPTURE CAULK AND PAINT, AND WHY THE 500 PPM MAX?] AND 3) DO I NEED TO WORRY ABOUT PCB-CONTAINING ELECTRICAL EQUIPMENT IN SCHOOLS OR OTHER THINGS BESIDES WHAT IS LISTED IN THIS DRAFT DEFINITION?,

3. Title II of TSCA contains the following definition: (12) RESPONSE ACTION.—The term ''response action'' means methods that protect human health and the environment from asbestos-containing material material. Such methods include methods described in chapters 3 and 5 of the Environmental Protection Agency's ''Guidance for Controlling Asbestos-Containing Materials in Buildings.'' Are these the analogous PCB documents listed below? If so, can you pls send the right URLs (all the links are broken), and if not, can you pls send the right materials?

EPA and Federal Partners

- Fact Sheets for Schools and Teachers about PCB-Contaminated Caulk from EPA provides information about PCBs in caulk used in some buildings, including schools, in the 1950s through the 1970s and offers suggestions on what to say to children about PCBs to encourage proper precautions. The website includes:
  - Fact Sheet for Schools: PCBs in Caulk School Checklist (PDF) (1pp, 106KB)
- PCB-Containing Fluorescent Light Ballasts in School Buildings: A Guide for School Administrators and Maintenance Personnelfrom EPA provides information on the risks posed by PCBs in light ballasts, how to properly handle and dispose of these items and how to properly retrofit school lighting fixtures to remove potential PCB hazards.
- PCBs in Caulk in Older Buildings on the EPA website offers background information, steps to minimize exposure, testing methods and a schools information kit.

4. Title II of TSCA refers to "least burdensome" in several places . Would it be better to delete these references?

5. Title II of TSCA tells EPA to prescribe transportation and disposal regulations for asbestos-containing waste. I am assuming that your 6(e) regs (and any revisions thereto) would cover this for PCBs, right?

6. Title II of TSCA requires warning labels to be placed in maintenance areas when inspections discover asbestos-containing materials. It is not clear to me that a similar label should be required for PCB-containing materials in schools given the different nature of these materials. Does EPA have a technical view?

7. Title II of TSCA says you can only update the asbestos removal guidance through rulemaking. Is it typical to require guidance updates to be done by rule, and if not, would it make sense to delete that requirement in this case?

8. Title II of TSCA describes an inspection standard and methodology that must be met for asbestos: Either a scanning electron microscope or a transmission electron microscope shall be used to determine the ambient interior concentration. In the absence of reliable measurements, the ambient exterior concentration shall be deemed to be—

> (A) less than 0.003 fibers per cubic centimeter if a scanning electron microscope is used, and
> (B) less than 0.005 fibers per cubic centimeter if a transmission electron microscope is used.

Does EPA still believe that this is the right methodology and standard? If not, what is?
Is there an analogous standard and methodology for PCBs and if so what is it?

9. As I gather from other TA, the Asbestos Trust Fund won't really exist anymore soon:

"The asbestos loan program is a direct loan program managed under the Credit Reform Act of 1990 (CRA). The issuance of new asbestos loans under the program officially ended in 1993. Subsequently, all remaining loan activity since 1993 has occurred for managing loan repayment/collection activities in accordance with the CRA and Debt Collection Act requirements. The Credit Reform Act of 1990 precludes

Agencies from repurposing funds for other needs. All asbestos loan related funds under the loan program are managed in accordance with the CRA, which specifically identifies how to manage collections received. Because FY 2016 serves as the final subsidy closing re-estimate year for the asbestos direct loan program, all of the remaining balances related to the Act requirements (including the $32,189.20 amount) are expected to be zeroed out prior to September 30, 2016 in close-out transactions at the end FY 2016. Although the funds may look available, they are not. The funds are tied to the Asbestos loan program, which is managed under the Credit Reform Act of 1990. The CRA identifies the process for final closing re-estimates. The final Asbestos loan closing re-estimate is in process and will sweep all of the account balances to Treasury prior to September 30, 2016."

But the statutory text does not talk about loans. It talks about grants. I'm confused about your TA as well as what we might need to do legislatively to reverse the outcome you've described above, or specify that the program is managed under the credit reform act of 1990. Can you please help me understand the statutory basis for your TA above as well as what a statutory remedy might be?

> For purposes of this sub- section, a ''violation'' means a failure to comply with respect to a single school building. The court shall order that any civil penalty collected under this subsection be used by the local educational agency for purposes of complying with this title. Any portion of a civil penalty remaining unspent after compliance by a local edu- cational agency is completed shall be deposited into the Asbestos Trust Fund established by section 5 of the Asbestos Hazard Emer- gency Response Act of 1986.

10. The MASK Act authorizes $10 mill/year for enforcement of asbestos requirements. If the bill was drafted to expand to PCBs as well, would EPA need more resources, and if so, how much?

11. Does the asbestos ombudsman still exist at EPA, and does the role work as envisioned? Should it be expanded to include PCBS?

12. Title II of TSCA required EPA to do a one-time study of where asbestos is in public bldgs.. The MASK Act requires these to be redone every 10 years. Would there be a benefit to a similar PCB study?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
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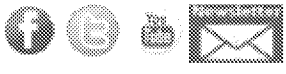
202-224-2742



Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 8/12/2016 4:07:33 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

Michal, standing room only the first two days on risk evaluation and prioritization. Lots of helpful views and comments. The fees meeting was a good start, need more work on a straw proposal that industry can respond to. Thanks,
Sven

Sven-Erik Kaiser
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, August 12, 2016 12:06 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

Thanks again! Hope the meetings went well - I was out of town but got some reports.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Friday, August 12, 2016 12:03 PM
To: Freedhoff, Michal (Markey)
Subject: RE: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

Michal – thanks for the followup questions. I'll check on the response. We have one remaining question on conditions of use and preemption that is underway (received 7/26). The PCB and asbestos responses are also close. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, August 12, 2016 11:57 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

Thanks very much - so you don't read anything in the act as saying you can only do RES on substances that have been designated high priority? How does that work in terms of the various timeframes and notice and comment periods required for prioritization and scoping of RE?

Could you, for example
Designate the flame retardants on the WP as a category/ies in the next few months
At the same time, designate a separate category of FRS (does category designation require notice/comment)?
When prioritization and RE rules go final, designate the second FR category as high priority, comply with all deadlines/scoping, and finish the two RES at the same time and do rulemaking at the same time?

Thanks!

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Friday, August 12, 2016 11:51 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

Michal,
This responds to the questions on TSCA section 26 and the first 10 chemicals.

Question:
First 10 Workplan chemicals and categories
What if there were some chemically analogous substances on the WP, but some chemically analogous substances that were NOT on the WP. Could the latter non-WP chemicals be evaluated/regulated as part of a first 10 WP group? ie do ALL the chemicals in the category need to be on the WP in order to be in the first 10 list?

First 10 Workplan chemicals and preemption
Say the scenario I have below works. You have 1 chemical on the WP, and you create a category that ropes in an additional 12 non-WP chemicals that are structurally analogous. What happens to those 12 non-WP chemicals if they hitch a ride on one of the first 10 WP REs by way of preemption? are they exempt from pause? If not, since they are not high-prioritized, what are they preemption-wise?

EPA Response: Based on our analysis of the statute to date, we are doubtful that TSCA authorizes EPA to establish a category (consisting of both Workplan chemical substances and non-Workplan chemical substances) and to then deem that category as one of the 10 Workplan chemical substances. Here is our reasoning:

- Section 26(c) establishes a rule of statutory construction for understanding how the rest of TSCA operates with respect to a category: "any reference in this Act to a chemical substance . . . (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance . . . in such category)"

- Turning to section 6(b)(2)(A), the statute specifies that in order to be among the initial 10, a chemical substance must be "drawn from the 2014 update of the TSCA Work Plan."

- Applying the rule of statutory construction from section 26(c) to the command in section 6(b)(2)(A), this seems to transform the requirement that a chemical substance be drawn from the Workplan into a requirement that "each chemical substance" in the category be drawn from the Workplan.

But EPA need not fold analogous non-Workplan chemical substances into a broader Workplan chemical category in order to proceed expeditiously with these non-Workplan analogues. TSCA gives EPA the flexibility to start a risk evaluation on a chemical substance that has not been identified as a Workplan chemical substance, designated as a high priority substance, or requested by industry. Thus, EPA could simply start risk evaluations on certain non-Workplan chemical substances at the same time that it starts risk evaluations on the analogous Workplan chemical substances. With respect to pause preemption, there would be no pause preemption for the non-Workplan analogues unless and until EPA designated them as high priority substances under section 6(b)(1)(B)(i).

For example, EPA could use its category authority to create two categories. The first would be a set of chemically analogous substances, all of which were drawn from the Workplan. The second would be a set of further chemically analogous substances, not drawn from the Workplan. EPA could identify the first category under section 6(b)(2)(A) and start a risk evaluation accordingly. EPA would not identify the second category under section 6(b)(2)(A), but could nonetheless start a risk evaluation on it, in tandem with the first category.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, July 19, 2016 3:18 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

And, actually, a second followup here – say the scenario I have below works. You have 1 chemical on the WP, and you create a category that ropes in an additional 12 non-WP chemicals that are structurally analogous. What happens to those 12 non-WP chemicals if they hitch a ride on one of the first 10 WP REs by way of preemption? are they exempt from pause? If not, since they are not high-prioritized, what are they preemption-wise?

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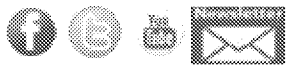
Connect with Senator Markey



From: Freedhoff, Michal (Markey)
Sent: Tuesday, July 19, 2016 2:49 PM
To: 'Kaiser, Sven-Erik'
Subject: RE: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

As a follow-up question – what if there were some chemically analogous substances on the WP, but some chemically analogous substances that were NOT on the WP. Could the latter non-WP chemicals be evaluated/regulated as part of a first 10 WP group? ie do ALL the chemicals in the category need to be on the WP in order to be in the first 10 list?

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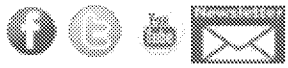

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, July 19, 2016 12:17 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

Michal,
This responds to the inquiry on using TSCA section 26 for the first 10 Workplan chemicals. You ask whether EPA believes it would be legally defensible to deem a category of chemically analogous Workplan chemicals to be a single chemical substance, for purposes of section 6(b)(2)(A) (EPA to commence risk evaluations for 10 chemical substances within 180 days of enactment). We believe this would be a legally defensible exercise of EPA's authority under 26(c).

EPA has broad discretion under section 26(c) to define chemical categories, including based on similar uses and similar chemical properties. With respect to such categories, section 26(c) establishes a general rule of construction that applies throughout the whole Act: "any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category." Thus, one of the 10 chemical substances referenced in 6(b)(2)(A) could be actually be a category that EPA established under 26(c).

The question you raise is not beyond debate, but we believe ours is the better reading of the statute. Congress knew about the existence of 26(c) at the time TSCA was amended to add 6(b)(2)(A), and yet did not limit 26(c) to prevent it from being applied to 6(b)(2)(A). We therefore believe that the stronger implication is that Congress did not intend to modify 26(c) so that it applies more narrowly in the context of 6(b)(2)(A). Furthermore, in terms of section 6 implementation, a category of chemically analogous Workplan chemicals would take the functional place of a single chemical substance – EPA could practicably issue a single risk evaluation for that category and address any unreasonable risk by a single rule.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, July 07, 2016 3:22 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TSCA question followup

HI Sven

In the call we had a couple weeks ago, it sounded like OGC hadn't yet made a determination about whether you can use the section 26 category authority for the first 10 WPs (ie, group flame retardants or pigments even though they are not necessarily grouped on the WP itself). Has that been figured out yet?

I'm getting increasing numbers of requests for EJM to weigh in on various chemicals and am trying to sort out whether it makes any sense for him to do so.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
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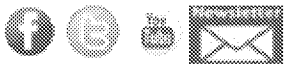

Message

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Sent: 8/12/2016 4:02:55 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: RE: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

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Sent: Friday, August 12, 2016 11:57 AM
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Subject: Re: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

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Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
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From: Kaiser, Sven-Erik
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To: Freedhoff, Michal (Markey)
Subject: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

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Sent: Tuesday, July 19, 2016 3:18 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

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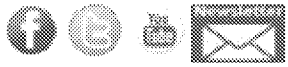
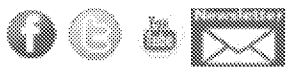


From: Freedhoff, Michal (Markey)
Sent: Tuesday, July 19, 2016 2:49 PM
To: 'Kaiser, Sven-Erik'
Subject: RE: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

As a follow-up question – what if there were some chemically analogous substances on the WP, but some chemically analogous substances that were NOT on the WP. Could the latter non-WP chemicals be evaluated/regulated as part of a first 10 WP group? ie do ALL the chemicals in the category need to be on the WP in order to be in the first 10 list?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, July 19, 2016 12:17 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

Michal,
This responds to the inquiry on using TSCA section 26 for the first 10 Workplan chemicals. You ask whether EPA believes it would be legally defensible to deem a category of chemically analogous Workplan chemicals to be a single chemical substance, for purposes of section 6(b)(2)(A) (EPA to commence risk evaluations for 10 chemical substances within 180 days of enactment). We believe this would be a legally defensible exercise of EPA's authority under 26(c).

EPA has broad discretion under section 26(c) to define chemical categories, including based on similar uses and similar chemical properties. With respect to such categories, section 26(c) establishes a general rule of construction that applies throughout the whole Act: "any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category." Thus, one of the 10 chemical substances referenced in 6(b)(2)(A) could be actually be a category that EPA established under 26(c).

The question you raise is not beyond debate, but we believe ours is the better reading of the statute. Congress knew about the existence of 26(c) at the time TSCA was amended to add 6(b)(2)(A), and yet did not limit 26(c) to prevent it from being applied to 6(b)(2)(A). We therefore believe that the stronger implication is that Congress did not intend to modify 26(c) so that it applies more narrowly in the context of 6(b)(2)(A). Furthermore, in terms of section 6 implementation, a category of chemically analogous Workplan chemicals would take the functional place of a single chemical substance – EPA could practicably issue a single risk evaluation for that category and address any unreasonable risk by a single rule.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, July 07, 2016 3:22 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TSCA question followup

HI Sven

In the call we had a couple weeks ago, it sounded like OGC hadn't yet made a determination about whether you can use the section 26 category authority for the first 10 WPs (ie, group flame retardants or pigments even though they are not necessarily grouped on the WP itself). Has that been figured out yet?

I'm getting increasing numbers of requests for EJM to weigh in on various chemicals and am trying to sort out whether it makes any sense for him to do so.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 8/12/2016 3:54:38 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey Inquiry on Nanoscale Substances and Conditions of Use

Michal,
This responds to the inquiry on nanoscale substances and conditions of use.

Question: In the past we've talked about a chemical substance used as part of a mixture qualifying as a condition of use of that substance. What about a nanocrystalline (or thin film) form of a chemical substance? EPA's nanotechnology policy is not to deem nano-versions of things to be new chemicals because their molecular structures are identical to the bulk form – but would a nanocrystalline form constitute a different condition of use in the same way a substance used in a mixture does?

EPA Response: A form in which a substance is manufactured or processed could be designated as a condition of use. Thus, manufacture or processing in nanoscale form (in a film or otherwise) could be so designated. Note that EPA has never stated that manufacture or processing of a substance in nanoscale form constitutes a use that must be restricted or limited.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, July 21, 2016 5:48 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: question on conditions of use

Sven

In the past we've talked about a chemical substance used as part of a mixture qualifying as a condition of use of that substance. What about a nanocrystalline (or thin film) form of a chemical substance? EPA's nanotechnology policy is not to deem nano-versions of things to be new chemicals because their molecular structures are identical to the bulk form – but would a nanocrystalline form constitute a different condition of use in the same way a substance used in a mixture does?

Thx
m

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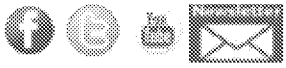

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From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 8/12/2016 3:36:18 PM
To: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]
Subject: Sen. Markey Inquiry on Partial Risk Evaluations

Michal,
This responds to the request on partial risk evaluations and preemption.

Question: EPA's partial RE chemicals will result in 6(a) rules – but will never have been subjected to section 6(b)(4)(D), nor met its requirements when EPA was first initiating the partial-REs. Is there an argument (even a tenuous one) to be made that the partial RE chemicals would not be subjected to preemption because section 18 was clearly referring to chemicals that EPA studies in the FUTURE, not chemicals it has already studied but not yet regulated?

EPA Response: EPA believes there is a reasonable argument that a state statute, criminal penalty, or administrative action to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, or use of a so called partial RE chemical will not be preempted under TSCA section 18(a)(1)(B). The extent of preemption under section 18(a)(1)(B) is "consistent with the scope of the risk evaluation under section (6)(b)(4)(D)." EPA's rulemaking authority for the so called partial RE chemicals is in section 26(l)(4), which provides EPA authority to publish section 6(a) rules for chemical substances for which completed risk assessments were published prior to the date of enactment of FRL21, "consistent with the scope of the completed risk assessment." Our position is that the risk assessments that have been completed and will form the basis of those rulemakings do not need to conform to the risk evaluation requirements of section 6(b). As section 26(l)(4) uses the term "risk assessments," not the term "risk evaluations," while the preemption provision utilizes the term "risk evaluations," there is clearly an argument that preemption does not attach to the rulemakings based on the previously completed risk assessments. Therefore, it is reasonable to argue that a section 6(a) rule promulgated under the authority of section 26(l)(4) will not preempt a state law or action on that chemical under section 18(a)(1)(B).

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Monday, July 18, 2016 2:18 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: partial RE question

Hi Sven

Section 18 describes the scope of preemption as follows:

> 18(a)(1)(B) CHEMICAL SUBSTANCES FOUND NOT TO PRESENT AN UNREASONABLE RISK OR RESTRICTED.—A statute, criminal penalty, or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

(i) for which the determination described in section 6(i)(1) is made, consistent with the scope of the risk evaluation under section (6)(b)(4)(D); or

(ii) for which a final rule is promulgated under section 6(a), after the effective date of the rule issued under section 6(a) for the chemical substance, consistent with the scope of the risk evaluation under section (6)(b)(4)(D).

18(c)(3) with respect to subsection (a)(1)(B), the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to section 6(a) or 6(i)(1); or

Section 6(b)(4)(D) states

(D) SCOPE.—The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider, and, for each designation of a high-priority chemical substance, ensure not less than 12 months between the initiation of the prioritization process for the chemical substance and the publication of the scope of the risk evaluation for the chemical substance, and for risk evaluations conducted on chemical substances that have been identified under paragraph (2)(A) or selected under subparagraph (E)(iv)(II) of this paragraph, ensure not less than 3 months before the Administrator publishes the scope of the risk evaluation.

EPA's partial RE chemicals will result in 6(a) rules – but will never have been subjected to section 6(b)(4)(D), nor met its requirements when EPA was first initiating the partial-REs. Is there an argument (even a tenuous one) to be made that the partial RE chemicals would not be subjected to preemption because section 18 was clearly referring to chemicals that EPA studies in the FUTURE, not chemicals it has already studied but not yet regulated?

Thanks
michal

Michal Ilana Freedhoff, Ph.D.
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202-224-2742

Connect with Senator Markey

Appointment

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/27/2015 2:08:06 PM
To: 'Zipkin, Adam (Booker)' [Adam_Zipkin@booker.senate.gov]; Fowler, Jamie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b74e8771b8049e5bde0f26dc5b1de97-JFowler6]

Subject: Sen. Booker TSCA TA Request on Compound 1080
Location: call in Ex. 6 - Personal Privacy, code Ex. 6 - Personal Privacy

Start: 7/27/2015 5:00:00 PM
End: 7/27/2015 6:00:00 PM
Show Time As: Tentative

Adam,
We're booked for 1pm today. I have a conflict and my colleague Jamie Fowler will be the congressional liaison on the call. Please let me know if any questions. Thanks,
Sven

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Monday, July 27, 2015 7:17 AM
To: Kaiser, Sven-Erik
Subject: Re: Sen. Booker TSCA TA Request on Compound 1080

Hi Sven I hope you had a nice weekend! Here are my questions. I could do a call today at 1:00, or we could push back if a little more time would be helpful on your side.

1) Are there many other EPA approved "predacides" other than Compound 1080 and Sodium Cyanide? I am not looking for an exhaustive list, but rather to understand the approximate size of the universe – if those two are the only ones or if there are potentially dozens/hundreds of others out there.

2) If there are other predacides besides Compound 1080 and Sodium Cyanide, are they all approved only for the same use – livestock protection – or are there other approved uses of predacides?

3) On our last call, EPA advised that the 40 CFR 152.5 definition of pests has been revised over time – that one definition existed until July 3, 1975, that a second definition was in place until 1988, and the current definition from 1988 to present. I don't remember if it was stated on the call whether there were rulemakings with public comment when the pest definition was revised in 1975 and 1988? If so, can EPA help me get copies?

4) For Compound 1080 and Sodium Cyanide, are they manufactured in the US for export as well as domestic use? If export is happening, what if any controls are in place for their transport and use in other countries?

Thanks! Adam

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, July 24, 2015 05:29 PM
To: Zipkin, Adam (Booker)

Subject: Re: Sen. Booker TSCA TA Request on Compound 1080

Adam,
David can do a call Monday anytime before 2 pm. Can you give me an idea of your questions so I get the right folks on the line. Thanks,
Sven

On Jul 24, 2015, at 4:20 PM, "Zipkin, Adam (Booker)" <Adam_Zipkin@booker.senate.gov> wrote:

Sven – I had a few follow up questions -- might it be possible to talk with David again on Monday?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, July 23, 2015 10:27 AM
To: Zipkin, Adam (Booker) <Adam_Zipkin@booker.senate.gov>
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Great – please call Ex. 6 - Personal Privacy, code Ex. 6 - Personal Privacy at 4:30 pm. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Thursday, July 23, 2015 10:26 AM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

4:30 yes thanks!

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, July 23, 2015 10:20 AM
To: Zipkin, Adam (Booker) <Adam_Zipkin@booker.senate.gov>
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Adam,
Following up on yesterday's call, are you available at 4:30pm today - I've got senior folks from the pesticides office and OGC lined up. Please let me know if 4:30 today works. Thanks,
Sven

Sven-Erik Kaiser
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Wednesday, July 22, 2015 9:18 AM
To: Kaiser, Sven-Erik
Subject: Re: Sen. Booker TSCA TA Request on Compound 1080

Thanks - 3:30?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, July 22, 2015 09:13 AM
To: Zipkin, Adam (Booker)
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Adam,
Available today for a call 10-11:30 and after 3pm. Thanks,
Sven

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From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Tuesday, July 21, 2015 8:07 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Sven that would be great -- I would be interested to talk to any attorney that knows both. Please let me know when might be a good time. Adam

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, July 21, 2015 11:46 AM
To: Zipkin, Adam (Booker) <Adam_Zipkin@booker.senate.gov>
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Adam,
On further reflection here, if you want to discuss further about the relationship between TSCA and FIFRA, I can offer a call with one of our attorneys who handles both statutes (sort of like speaking two languages). Thanks,
Sven

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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Monday, July 20, 2015 9:15 AM
To: 'Zipkin, Adam (Booker)'
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Adam,
FIFRA includes pests – defined as living organisms that occur where they are not wanted or that cause damage to crops or humans or other animals. Examples include:

- insects,
- mice and other animals (this is where the coyotes come in)
- unwanted plants (weeds),
- fungi, and
- microorganisms such as bacteria and viruses.

Please let me know if you would like a call with FIFRA folks on sodium fluoroacetate. Thanks,
Sven

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1200 Pennsylvania Ave., NW (1305A)
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From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Sunday, July 19, 2015 2:49 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Thanks Sven -- that is helpful, as I am still learning. Please see attached article which states "Sodium Fluoroacetate, also highly toxic, is a "restricted use" chemical, that is only approved for use to protect livestock from coyotes and can only be used by a licensed professional" – so that approved use (protecting livestock from coyotes) is pursuant to FIFRA? When I think of pesticides, I tend to think of chemicals used to kill bugs, not coyotes -- but sounds like definition of "pest" may be broader than I thought and include animals such as coyotes?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, July 17, 2015 7:17 PM
To: Zipkin, Adam (Booker)
Subject: Sen. Booker TSCA TA Request on Compound 1080

Adam –

Sodium fluoroacetate is registered for use as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Like all chemicals with pesticidal uses, this chemical is currently outside of TSCA's jurisdiction to the extent that it is "manufactured, processed, or distributed in commerce for use as a pesticide." See the definition of "chemical substance" at TSCA Section 3(2)(B)(ii).

Please clarify whether you are inquiring about a TSCA ban of the non-pesticidal uses of sodium fluoroacetate, or about a TSCA ban of the pesticidal uses of sodium fluoroacetate. (The latter would require altering the TSCA definition of "chemical substance"). This clarification will help us to scope our response accordingly.

Thanks,

Sven

On Jul 17, 2015, at 4:07 PM, "Zipkin, Adam (Booker)" <Adam_Zipkin@booker.senate.gov> wrote:

Hello Sven. Within my office the idea is being discussed of a possible amendment to Section 6 of TSCA to prohibit the use, production, sale, importation, or exportation of sodium fluoroacetate (known as 'Compound 1080'). At this point I have not proposed adding this to the bill sponsors, and wanted to see if EPA had any TA and/or history with Compound 1080 that you could share? Thanks. Adam

Message

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Sent: 7/24/2015 8:26:41 PM
To: Zipkin, Adam (Booker) [Adam_Zipkin@booker.senate.gov]
Subject: Re: Sen. Booker TSCA TA Request on Compound 1080

I'll let folks know and get some availabilities

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Sent: 7/22/2015 1:25:16 PM
To: 'Zipkin, Adam (Booker)' [Adam_Zipkin@booker.senate.gov]
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Adam,
Sounds good for 3:30 pm today. Please call Ex. 6 - Personal Privacy code Ex. 6 - Personal Privacy Thanks,
Sven

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Subject: Re: Sen. Booker TSCA TA Request on Compound 1080

Thanks - 3:30?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, July 22, 2015 09:13 AM
To: Zipkin, Adam (Booker)
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Adam,
Available today for a call 10-11:30 and after 3pm. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Tuesday, July 21, 2015 8:07 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Sven that would be great -- I would be interested to talk to any attorney that knows both. Please let me know when might be a good time. Adam

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, July 21, 2015 11:46 AM
To: Zipkin, Adam (Booker) <Adam_Zipkin@booker.senate.gov>
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Adam,
On further reflection here, if you want to discuss further about the relationship between TSCA and FIFRA, I can offer a call with one of our attorneys who handles both statutes (sort of like speaking two languages). Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Kaiser, Sven-Erik
Sent: Monday, July 20, 2015 9:15 AM
To: 'Zipkin, Adam (Booker)'
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Adam,
FIFRA includes pests – defined as living organisms that occur where they are not wanted or that cause damage to crops or humans or other animals. Examples include:

- insects,
- mice and other animals (this is where the coyotes come in)
- unwanted plants (weeds),
- fungi, and
- microorganisms such as bacteria and viruses.

Please let me know if you would like a call with FIFRA folks on sodium fluoroacetate. Thanks,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Zipkin, Adam (Booker) [mailto:Adam_Zipkin@booker.senate.gov]
Sent: Sunday, July 19, 2015 2:49 PM
To: Kaiser, Sven-Erik
Subject: RE: Sen. Booker TSCA TA Request on Compound 1080

Thanks Sven -- that is helpful, as I am still learning. Please see attached article which states "Sodium Fluoroacetate, also highly toxic, is a "restricted use" chemical, that is only approved for use to protect livestock from coyotes and can only be used by a licensed professional" – so that approved use (protecting livestock from coyotes) is pursuant to FIFRA? When I think of pesticides, I tend to think of chemicals used to kill bugs, not coyotes -- but sounds like definition of "pest" may be broader than I thought and include animals such as coyotes?

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Friday, July 17, 2015 7:17 PM
To: Zipkin, Adam (Booker)
Subject: Sen. Booker TSCA TA Request on Compound 1080

Adam –

Sodium fluoroacetate is registered for use as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Like all chemicals with pesticidal uses, this chemical is currently outside of TSCA's jurisdiction to the extent that it is "manufactured, processed, or distributed in commerce for use as a pesticide." See the definition of "chemical substance" at TSCA Section 3(2)(B)(ii).

Please clarify whether you are inquiring about a TSCA ban of the non-pesticidal uses of sodium fluoroacetate, or about a TSCA ban of the pesticidal uses of sodium fluoroacetate. (The latter would require altering the TSCA definition of "chemical substance"). This clarification will help us to scope our response accordingly.

Thanks,

Sven

On Jul 17, 2015, at 4:07 PM, "Zipkin, Adam (Booker)" <Adam_Zipkin@booker.senate.gov> wrote:

Hello Sven. Within my office the idea is being discussed of a possible amendment to Section 6 of TSCA to prohibit the use, production, sale, importation, or exportation of sodium fluoroacetate (known as 'Compound 1080'). At this point I have not proposed adding this to the bill sponsors, and wanted to see if EPA had any TA and/or history with Compound 1080 that you could share? Thanks. Adam

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/23/2016 6:22:41 PM
To: Schmit, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7077ecbac4914a00ad465398f92bbe78-Schmit, Ryan]; Mclean, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=869a9152d655420594d8f94a966b8892-KMCLEAN]; Wills, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca379f4ec8204787ad79dcfda6071c12-JWILLS]
Subject: RE: Shimkus TSCA TA Request on section 26 - fees
Attachments: SEPW TSCA TA Fees Question; RE: Sen. Udall TSCA TA Request on User Fees; TSCA Views attachment.final.docx; CBO TSCA TA Request on HR 2576 cost estimates; CBO TA on House TSCA Bill Cost Estimates; Senate TSCA TA on Fees and Appropriations.docx; Review of senate cost estimate; HEC TSCA TA Request on Fees; RE: TSCA Reform TA - Fee Scenarios; TSCA Reform TA Fee Scenarios.docx

FYI – attached is past fees TA. We did some comparison in the views letter (third attachment). Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Schmit, Ryan
Sent: Wednesday, March 23, 2016 2:05 PM
To: Mclean, Kevin <Mclean.Kevin@epa.gov>; Wills, Jennifer <Wills.Jennifer@epa.gov>
Cc: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Shimkus TSCA TA Request on section 26 - fees

Jim asked me to check whether we're prepared to do this, before we agree.

Sent from my iPhone

On 23 Mar 2016, at 1:41 pm, Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov> wrote:

> TSCA Team,
> David McCarthy called asking if we could do a call this afternoon to go through the difference between the House and Senate fee sections. I suggested 5pm since we are already gathering. If okay, I'll give him the call number for the 5pm meeting. Thanks,
> Sven
>
> Sven-Erik Kaiser
> U.S. EPA
> Office of Congressional and Intergovernmental Relations
> 1200 Pennsylvania Ave., NW (1305A)
> Washington, DC 20460
> 202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/17/2015 2:53:43 PM
To: 'Susanne Mehlman' [Susanne.Mehlman@cbo.gov]
Subject: CBO TA on House TSCA Bill Cost Estimates

Susanne,

This responds to your earlier questions about fees in the House TSCA bill.

1. Pre-Manufacturing Notification (PMN) fees

Under the current fee structure, EPA will collect about $1.1 million in FY2015. With the cap removed under the House bill, if EPA is able to collect fees to "defray costs" at 100 percent of the cost of administering the new chemicals program, EPA estimates collecting up to $14 million.

2. CBI Penalties

The House bill establishes new authority for EPA to assess TSCA penalties against persons who receive confidential business information pursuant to section 14(a) and then proceed to improperly use or disclose such information. Specifically, section 9(h) of the bill (Page 38, lines 18-23) amends section 15 to make "any requirement of this title" subject to civil and criminal penalties set forth in Section 16 (e.g., up to $25,000 per/day civil penalties). In addition, section 14(f) is added by the bill, to provide that "[n]o person who receives information as permitted under subsection (a) may use such information for any purpose not specified in such subsection, nor disclose such information to any person not authorized to receive such information."

3. Manufacturer Requested Assessments

We have little reliable information on which to base an estimate. The number will depend on manufacturer balancing of the potential costs and benefits of requesting an evaluation. Currently, EPA undertakes about 10 assessments a year and this could be a default figure for manufacturer requests. The actual number of industry requests will be impacted by the relatively high cost of paying 100 percent for an assessment (current EPA funded assessments can be up to $1 million) and the uncertainty of the outcome due to potential follow on risk management action (currently 50 percent of EPA assessments lead to risk management action). It seems reasonable to expect a lower amount of manufacturer requested assessments to lead to risk management action since manufacturers would be less likely to submit assessment requests where risk management action is foreseeable. Note also that the cost of risk management actions would be wholly borne by EPA and currently can cost about $1.5 million each in program costs.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks.

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Susanne Mehlman [mailto:Susanne.Mehlman@cbo.gov]
Sent: Tuesday, June 16, 2015 10:43 AM
To: Kaiser, Sven-Erik
Subject: RE: House TSCA Bill

I am still looking over everything you sent BUT I will need more info on the fees.not sure what numbers to go with . I can assume similar levels to Senate bill.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/19/2015 8:30:23 PM
To: 'Amy Petz' [Amy.Petz@cbo.gov]
Subject: CBO TSCA TA Request on HR 2576 cost estimates

Amy,
This responds to your technical assistance request on cost estimates for HR 2576.

I am trying to determine how many chemical substances might be subject to section 6(a) regulations each year.

EPA Response: We do not have a lot of history to draw from to make a good estimate of how many risk management regulations would result from performing risk evaluations. For the five risk assessments completed on TSCA Work Plan chemicals, three were found to have risk that could require risk management and two did not. With sufficient caveats acknowledging the small sample size, you might be able to use an estimate of 40 percent of risk evaluations resulting in further risk management.

H.R. 2576 would direct EPA to conduct risk evaluations for at least 10 chemical substances annually. Would EPA be likely to conduct risk evaluations for more than 10 chemicals annually? If so, is there an estimate of how many EPA might evaluate?

EPA Response: HR 2576 would require EPA to initiate risk evaluations for at least 10 chemical substances per year. EPA would not be likely to initiate risk evaluations for more than 10 chemicals per year.

Also, how many PBT chemicals would EPA be likely to regulate each year under the expedited authority? I saw information that there could be 100 or more PBT chemicals, but it seems unlikely that EPA would issue section 6(a) rules for all of them in one year.

The PBT process laid out in the bill is a one-time process, separate from the ongoing assessment and managment of chemicals. Based on the requirements of HR 2576 and EPA's experience with Work Plan chemicals, we would likely narrow down the initial list of possible PBTs to several hundred needing further analysis and some subset of those would be candidates for risk management regulation. EPA would promulgate as many risk management regulations as we are appropriated resources.

The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
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Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Amy Petz [mailto:Amy.Petz@cbo.gov]
Sent: Thursday, June 18, 2015 4:16 PM
To: Kaiser, Sven-Erik
Subject: HR 2576 TSCA

Hi Sven,

We spoke a few weeks ago about S. 697, the Senate's TSCA reform bill. As you know, CBO is now reviewing H.R. 2576, the House's version. I review legislation for its impact to the private sector as required by the Unfunded Mandates Reform Act. I am trying to determine how many chemical substances might be subject to section 6(a) regulations each year. H.R. 2576 would direct EPA to conduct risk evaluations for at least 10 chemical substances annually. Would EPA be likely to conduct risk evaluations for more than 10 chemicals annually? If so, is there an estimate of how many EPA might evaluate? Also, how many PBT chemicals would EPA be likely to regulate each year under the expedited authority? I saw information that there could be 100 or more PBT chemicals, but it seems unlikely that EPA would issue section 6(a) rules for all of them in one year.

As Susanne probably mentioned, our timeframe for completing our analysis is very short. Any information would be greatly appreciated.

Thanks for your help,

Amy

--

Amy Petz
Analyst, Private-Sector Mandates Unit
Congressional Budget Office
(202) 226-2969
amy.petz@cbo.gov

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/18/2015 4:12:13 PM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]; 'McCarthy, David' [David.McCarthy@mail.house.gov]
Subject: HEC TSCA TA Request on Fees

Jerry,
Thank you for the technical assistance request. Current TSCA allows for collection of fees for Section 4 (testing) and Section 5 (new chemicals/PMNs). EPA is only collecting fees for pre-manufacturing notifications (PMNs). The PMN fee is collected for the review and processing of new chemical pre-manufacturing notifications submitted to EPA by the chemical industry. TSCA contains a cap on the amount the agency may charge for a PMN review. Fees collected for this activity do not come to the program and do not defray the agency's costs, but rather are deposited in the U.S. Treasury. EPA estimates that $1.1 million will be deposited in FY2016. The total cost for the PMN program is estimated to be $14-$17M. Therefore, 8% - 6.5% of costs are deposited in the U.S. Treasury (not directly defraying agency's costs).

Please let me know if any additional questions. Best,
Sven

Sven-Erik Kaiser
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Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Thursday, June 18, 2015 9:18 AM
To: Kaiser, Sven-Erik
Cc: McCarthy, David
Subject: Technical Assistance Request

Sven:

Could you please provide me TA on how much the Agency generally receives under TSCA imposed user fees? What percentage of the costs do the fees cover?

Thanks.

- Jerry

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/10/2016 5:04:47 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
CC: 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; 'Deveny, Adrian (Merkley)' [Adrian_Deveny@merkley.senate.gov]
Subject: RE: Sen. Udall TSCA TA Request on User Fees

Jonathan,
Last year we provided to CBO that current EPA funded assessments can be up to $1 million each and current risk management actions can cost about $1.5 million each – adding up to the $2.5 million figure you asked about. At this point, we don't have any reason to change the estimates based on the various versions of the bills under consideration. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Thursday, March 10, 2016 9:54 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: RE: Sen. Udall TSCA TA Request on User Fees

We have it somewhere that it costs approx. $2.5M from start to finish (on average to evaluate a chemical and then regulate it).

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, March 10, 2016 9:54 AM
To: Black, Jonathan (Tom Udall) <Jonathan_Black@tomudall.senate.gov>
Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: Sen. Udall TSCA TA Request on User Fees

Jonathan – checking. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Thursday, March 10, 2016 9:53 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>

Cc: Freedhoff, Michal (Markey) <Michal_Freedhoff@markey.senate.gov>; Deveny, Adrian (Merkley) <Adrian_Deveny@merkley.senate.gov>
Subject: User Fees

Sven, I'm trying to find T.A. that was already provided to me that explains the costs of risk evaluations and regulations of chemicals.

The only one I can find at the moment is this one. is there a way to track down other fee related T.A. that has been provided already?

Message

From: Cleland-Hamnett, Wendy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B84439FCDF02426ABD539D8BB6C9EF6F-CLELAND-HAMNETT, WENDY]
Sent: 2/23/2015 10:54:03 PM
To: Kaiser, Sven-Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac78d3704ba94edbbd0da970921271ff-SKAISER]; Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]; Wallace, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb92a9d14cc84b99a9049627ee2b0e48-Wallace, Ryan]
Subject: RE: TSCA Reform TA - Fee Scenarios

I thought they wanted to look at fees as a percentage of the new program. If they are looking at it as a percentage of current appropriated, it would be the following.

Jim: important to know whether you want to send the message at 20% that there would be no additional chemicals, which is how it works out with the numbers we've been using.

20% of $56M = $11.2M. This would buy no additional priority chemicals beyond baseline due to increased costs of implementing other provisions of CSIA

25% of $56M = $14M. This would buy 4 additional chemicals per year beyond baseline, for a total of 14 chemicals per year.

30% of $56M = $16.8M. This would buy 9 to 10 additional chemicals per year beyond baseline, for a total of 19 to 20 chemicals per year.

Wendy Cleland-Hamnett
Director
Office of Pollution Prevention & Toxics
Office of Chemical Safety and Pollution Prevention
202 564-3810 (O) 202 564-0575 (F)
cleland-hamnett.wendy@epa.gov

From: Kaiser, Sven-Erik
Sent: Monday, February 23, 2015 5:35 PM
To: Cleland-Hamnett, Wendy
Subject: FW: TSCA Reform TA - Fee Scenarios

Wendy – feedback from Dimitri. Perhaps I didn't describe it right. Apologies for the extra work. Thanks, Sven

Sven-Erik Kaiser
U.S. EPA
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1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Monday, February 23, 2015 5:15 PM
To: Kaiser, Sven-Erik; Black, Jonathan (Tom Udall)
Subject: RE: TSCA Reform TA - Fee Scenarios

In further looking at this it seems like you all went about the calculations in a strange way. You cannot add the estimated fees to the current "base" then calculate the percentage. 20% of current $56 million would be $11.2 million. In order to get $14 million in fees you would have to have 25% fees from the baseline number.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, February 23, 2015 4:41 PM
To: Karakitsos, Dimitri (EPW); Black, Jonathan (Tom Udall)
Subject: RE: TSCA Reform TA - Fee Scenarios

Dimitri and Jonathan,

We started with $56M as our current "base" for new and existing chemicals work. We then added fee amounts. The percentage was then calculated using the fees as a percentage of the new totals. We caveat that although there has been discussion of fees for new chemical submissions, those fees are not included here as either additional amounts or in the calculation of percentages.

At 20%, we estimate would raise $14M in fees, bringing the program total to $70M.

At 25%, we estimate would raise $19M in fees, bringing the program total to $75M.

At 30%, I calculated that we would raise $24M in fees, bringing the program total to $80M.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Friday, February 20, 2015 1:21 PM
To: Kaiser, Sven-Erik; Black, Jonathan (Tom Udall)
Subject: RE: TSCA Reform TA - Fee Scenarios

Sven – quick follow up here. Can you give me an idea of what EPA expects to raise at each fee percentage? We had a somewhat confusing discussion about each percentage being a percentage of what (if that makes sense). If we could know what numbers EPA calculated it would raise at 20%, 25%, and 30%, it would let us know the total pot you all were working from.

Please let me know if that makes sense or if you want to follow up and thanks for your help with this.

Dimitri

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, February 18, 2015 12:07 PM
To: Karakitsos, Dimitri (EPW); Black, Jonathan (Tom Udall)
Subject: TSCA Reform TA - Fee Scenarios

Jonathan and Dimitri,
In response to your request, please see attached technical assistance on fee scenarios. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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202-566-2753

Message

From: Berol, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A227F36CA9EE4EEB98A95CB22058DE43-DBEROL]
Sent: 6/25/2015 5:37:52 PM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]; Cleland-Hamnett, Wendy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b84439fcdf02426abd539d8bb6c9ef6f-Cleland-Hamnett, Wendy]
CC: Grant, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec6104b72cab42ba9b1e1da67d4288ae-Grant, Brian]; Mclean, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=869a9152d655420594d8f94a966b8892-KMCLEAN]; Wallace, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb92a9d14cc84b99a9049627ee2b0e48-Wallace, Ryan]; Kaiser, Sven-Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac78d3704ba94edbbd0da970921271ff-SKAISER]
Subject: Review of senate cost estimate

Jim and Wendy –

This is with respect to the likelihood that the Senate bill would result in a net $ 8 million savings to the government as a result of new fees exceeding new costs.

CBO's analysis appears to be based on the assumption that the "additional priorities" industry money ($ 7 million above the $18 million cap) would not be accompanied by additional offsetting costs beyond the flat $17 million. Brian and I gave some further consideration to whether this is legally plausible, by a scenario in which EPA receives a large number of requests to designate work plan chemicals as "additional priorities." Could EPA simply treat *those additional workplan priorities* as the chemicals that it uses to satisfy its throughput requirements under 4A, thereby accepting fees beyond $18 million without accepting additional expense beyond the baseline expense increase of $17 million? The drafting on this issue is less than crystal clear, but after some thought it seems to us that such a scenario would be inconsistent with the best reading of the bill.

The following provision from 26(c)(1)(2)(C) seems to apply to both the additional priority chemicals that are not on the workplan and those additional priority chemicals that are on the workplan:

- "the number of additional priority requests stipulated under subparagraph (A) **is in addition to** the total number of high-priority chemicals identified under subsections (a)(2) and (b)(3)" (emphasis added, referring to the basic throughput requirements under 4A)

Based on this reading, it seems that every dollar received under the Senate bill's additional priorities system would be accompanied by either $2 of costs (50% defrayment of workplan chemicals) or $1 of costs (100% defrayment of non-workplan chemicals)

David Berol
U.S. EPA Office of General Counsel
202-564-6873
berol.david@epa.gov

This information is provided by EPA as technical assistance in response to a congressional request. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the information.

FEE SCENARIOS FOR EXISTING CHEMICALS PROGRAM (2/18/15)

Assumptions based on congressional technical assistance request:

- "priority chemicals per year" means # of chemicals in some phase of risk assessment/safety determination or risk management

- # of chemicals assumes a steady state – as a chemical is removed, a new one starts the process

- "Baseline" equals 10 chemicals

- Fees @ 20% of program would fund:
  - 4 priority chemicals per year above "baseline" = Total 14 priority chemicals plus running other aspects of the existing chemicals program

- Fees @ 25% of program:
  - 14 priority chemicals per year above "baseline" = Total 24 priority chemicals plus running other aspects of the existing chemicals program

- Fees @ 30% of program:
  - 24 priority chemicals per year above "baseline" = Total 34 priority chemicals plus running other aspects of the existing chemicals program

Administration Views on the TSCA Reform Bills (H.R. 2576 and S. 697)

Deadlines for Action

Essential to a reformed TSCA are statutory mechanisms that drive EPA action to review chemicals and regulate those that are unsafe. In its Principles, the Administration calls for "clear, enforceable and practicable deadlines."

On this point, the Senate bill is preferable. It provides certainty about the progress that the EPA is required to make reviewing chemicals. The Senate bill imposes an absolute requirement to have completed or at least begun a certain number of assessments (20 high-priority assessments within 3 years, and 25 high-priority assessments within 5 years), and imposes a requirement to repopulate the high-priority list as each assessment is completed until all chemicals on the TSCA inventory have been evaluated.

Elimination of the "Least Burdensome" Requirement

The Administration supports the elimination of current TSCA's "least burdensome" requirement, which the court in *Corrosion Proof Fittings* – an often-cited TSCA case – has interpreted to impose a tremendous analytical burden on the agency. The EPA's failure to meet this requirement – after over a decade of rulemaking and thousands of pages of analytical record – resulted in the overturning of the asbestos rule. Both the House and Senate bills include new, different considerations for the EPA when selecting among risk management measures ("Analysis for Rulemaking" in Section 6(d)(4) of TSCA as amended by the Senate bill and "Requirements for Rule" at Section 6(c)(1)(B) of TSCA as amended by the House bill).

Whatever the resolution, the Administration urges Congress to establish considerations that are sufficiently circumscribed so that the EPA will not be required to assess the costs and benefits of an indefinite number of regulatory alternatives, or otherwise be obligated to pursue alternatives analyses beyond the realm of analytic practicability. Such requirements would likely undermine the operation of a revised law even if it contains a clear safety standard and practicable deadlines.

The Administration prefers the consideration requirements under the Senate bill because they expressly provide that they do not extend the EPA's analytical burden beyond what can be practicably accomplished, based on reasonably available information. Subject to these bounds, the EPA would be required to consider the costs and benefits of alternative methods to achieve the safety standard for a particular chemical substance. The EPA would also be required to incorporate such consideration into a statement accompanying each risk management rule, which would then be part of the administrative record for the rule, and thus allow for judicial review of the adequacy of the agency's reasoning.

By contrast, the House bill requires the EPA to defend one of two affirmative alternative findings in order to issue a risk management rule: either that the rule is cost effective or that a non-cost effective alternative is necessary. The scope of analysis required for making these findings may be bounded by the information that is "reasonably ascertainable," under section

6(c)(1)(A). Even if the analysis is so bounded, this provision leaves uncertainty about how many cost effective options the EPA would have to analyze and reject as inadequate before selecting a non-cost effective option.

Prioritizing Chemicals for Review

The Administration's Principles make clear that the EPA should have the authority to prioritize chemicals for review based on relevant risk and exposure considerations. Both the House and Senate bills also include provisions that would allow manufacturers to identify their own priority chemicals for review by the EPA. If a similar mechanism is included in a final bill, it is essential that it not overrun the EPA's ability to prioritize chemical reviews. For this reason, the Administration strongly prefers the Senate version since that bill explicitly caps the number of risk evaluations that can be initiated based solely on manufacturers' interest and it requires both full payment of the costs of the assessment and, if necessary, defrayment of the ensuing costs to develop risk management regulation. Without a meaningful cap or similar measures, manufacturer priorities have the potential to overrun the EPA's chemicals management program and prevent the agency from addressing chemicals with greater potential risks. Without appropriate funding for risk management costs, the EPA may not be able to complete work on manufacturer priorities as Congress presumably intended. The House bill has no cap on manufacturer initiated risk evaluations, and no requirement for industry to pay for the risk management actions that the EPA may find itself legally obligated to undertake after completing the requested risk evaluations. The House language would allow the EPA to put risk evaluations on hold if it receives more industry requests than it has resources to handle, but this provision could be interpreted to allow the EPA to put on hold *EPA initiated evaluations* as well as manufacturer initiated evaluations.

Sustained Source of Funding

The Administration's Principles state that the EPA work under TSCA should be "adequately and consistently funded" and that manufacturers should "support the costs of Agency implementation." The Administration is pleased that both the House and Senate modify Section 26 to establish a dedicated TSCA implementation fund and expand fee collection authority.

The House bill's fee provisions would not defray the EPA's costs of reviewing existing chemicals (aside from those initiated by industry) or any of the costs associated with regulatory risk management actions. It could also be argued that the fees that the EPA could collect for the submission of test data would not cover the EPA's costs to assess the data as part of a chemical risk evaluation.

The Administration prefers the Senate bill's funding provisions, which explicitly add new fee collection authority for the costs of reviewing confidential business information (CBI) claims, reviewing notices under section 5, making prioritization decisions, conducting and completing safety assessments, and conducting rulemakings.

The EPA should have broad authority to use its fees to cover the costs of agency implementation. Giving the EPA this authority generally would avoid the concerns raised above about the EPA's spending authority in specific scenarios. Further, imposing spending caps and the Senate bill's minimum appropriations requirements for assessing fees could still create implementation challenges.

Implementation Challenges

The Administration encourages Congress not to impose on the EPA extensive, prescriptive requirements to develop policy and procedure documents. The dedication of resources to meeting these process development expectations could frustrate the EPA's efforts to timely and directly implement the substantive requirements of TSCA.

The Senate bill, particularly in sections 3A and 4A, establishes pressing deadlines for the EPA to develop various policy and procedure documents, and prescribes numerous specifications for the content of such documents. Meeting these document generation requirements may unnecessarily slow progress on more substantive issues, limit the EPA's flexibility to allocate resources appropriately, and lead to burdensome litigation regarding the process development requirements.

The EPA has already developed and promulgated numerous policies, procedures, and scientific guidances. The EPA continues to invest resources in hosting open public debate on pressing scientific issues and the development of policies and guidances, and does so in accordance with existing objectivity and transparency requirements. For highly impactful or controversial issues, the EPA continues to engage the National Academies of Science, Engineering and Medicine to ensure the development of robust policies and procedures.

The Administration strongly prefers the House bill on this matter since it only requires the EPA to develop new policies, procedures, and guidelines to the extent necessary. If the detailed procedural specifications of the Senate bill are retained, the Administration supports also retaining the accompanying savings provisions that the Senate bill adds to TSCA Section 6(b), which allow the EPA to continue its ongoing work to protect public health and the environment while the required policies, procedures and guideline are under development.

Safety Standard

The Administration's Principles call for a new safety standard that is "based on sound science and reflect[s] risk-based criteria protective of human health." The Administration encourages Congress to apply the new safety standard consistently throughout the revised statute.

If a clear directive for the EPA to apply the new safety standard is expressed only with respect to section 6, as is the case in the House bill, that could create uncertainty as to what standard would apply to EPA actions under other provisions of TSCA where the phrase "unreasonable risk" appears (for example, under sections 4, 5, 7, 12 and 14). Providing an upfront definition of the safety standard, as in the Senate bill, is one way to better ensure uniform

application of the new standard to all actions under TSCA. Alternatively, "unreasonable risk" could be redefined in each instance it appears.

On a related point, there are several provisions in section 6 of the House bill that could possibly be read to suggest that different standards apply in section 6(a) rulemakings in different scenarios. For example, the EPA is authorized to promulgate non-cost-effective requirements if "necessary to protect against the identified risk" (section 6(c)(1)(B)). It might be argued that this language provides a different risk management standard from section 6(a) (regulation must ensure that a chemical substance "no longer presents or will present an unreasonable risk"). A similar issue appears with respect to regulation of replacement parts (section 6(c)(1)(D)) and articles (section 6(c)(1)(E)).

In general, the Administration appreciates that both the House and Senate bills allow for exemptions to otherwise applicable risk management requirements where necessary to maintain a critical use, or to protect national security or avoid disruption to the national economy. This is consistent with Administration Principle 3, which states that risk management decisions should take into account sensitive subpopulations, cost, availability of substitutes and other relevant considerations. This principle should be consistent across the relevant risk management provisions of the bills.

Finally, some confusion might be caused by the House bill provision that requires rulemaking for persistent, bioaccumulative and toxic (PBT) chemicals under section 6(a) to reduce likely exposure to the extent practicable (section 6(i)(3)). Sections 6(a) and 6(i) actually impose different rulemaking standards. Both the section 6(a) rulemaking standard and several of the considerations required in promulgating section 6(a) rules (which appear in section 6(c)) assume that the EPA has identified specific risks as unreasonable. However, the EPA may not have actually performed a risk evaluation for a particular PBT which is required (under section 6(i)) to be the subject of a 6(a) risk management rulemaking.

Regulatory Flexibility

The House bill retains the current TSCA section 6(a) menu of requirements the EPA can impose in section 6 rulemakings. Although this menu is extensive, it is not comprehensive. Specifically, the menu expressly authorizes the EPA to regulate the manufacture, processing and distribution in commerce of a chemical substance only through a complete ban or ban for specific uses, or through quantity or concentration limitations. In contrast, with respect to commercial use, section 6(a) gives the EPA broader authority to impose requirements "prohibiting *or otherwise regulating*" the use (section 6(a)(5)). In operation, this menu may drive regulation that is more burdensome than necessary. The Administration prefers the approach in section 6(d) of the Senate bill, which includes "catch-all" regulatory authorities.

Safety of New Chemicals

Under current TSCA, manufacturing and processing of new chemicals can commence upon expiration of the premanufacture notice review period without the EPA determining whether or not those chemicals are safe. As stated in the Administration's Principles 2 and 4, the

EPA should conclude whether or not new chemicals meet the safety standard before those chemicals are allowed to enter the market. As such, the Administration supports the Senate bill requirement that the EPA make an affirmative safety determination regarding new chemicals.

Transparency and Confidential Business Information

The Administration's Principles outline certain improvements regarding the transparency of chemical information. The Administration is pleased that both the House and Senate make improvements to substantiation requirements for CBI claims. The House bill requires substantiation of new CBI claims, while the Senate bill requires substantiation of both new and existing claims. The Administration also supports new authority in both bills for the EPA to appropriately share CBI with others when necessary to protect public health and safety.

However, the Administration is concerned with a provision in the House bill that would allow "formulas (including molecular structures)" of a chemical substance to be withheld as CBI in health and safety studies. Under current section 14, formula information in health and safety studies can be protected as CBI only if it discloses process information. Thus, the House provision would decrease transparency and shield from the public relevant chemical information (in some cases, the specific identity of a chemical that is the subject of a health and safety study).

Authority to Require Development of Information

Another significant problem under current TSCA is the difficulty of requiring the development of information on chemicals for which information is lacking. Both bills address a major contributor to this problem: the lack of authority to require testing by order. The other contributor is substantive: section 4 of TSCA currently requires the EPA to either demonstrate that a chemical "may present an unreasonable risk," before it can require testing, or else that there is already substantial production and substantial release of or exposure to the chemical substance. The obligation to make these demonstrations has created difficulties for the EPA in requiring testing necessary to assess the safety of chemicals.

Both the House and Senate bills give the EPA new authority to require testing for specific purposes, including during risk evaluations. Under the new House authority, however, the EPA must first make a risk-based finding before initiating a risk evaluation. Although the bar is fairly low ("may present an unreasonable risk...because of potential hazard and a potential route of exposure…"), it could have the effect of perpetuating the difficulties the EPA has encountered under current TSCA. Outside of the risk evaluation context, the House bill could still require the EPA to make a "may present an unreasonable risk" finding before requiring testing under section 4. The Administration encourages Congress to ensure that the EPA is given the necessary authority and tools to obtain information relevant to determining the safety of chemicals.

Chemicals in Articles

The Administration encourages Congress to look closely at provisions in both the Senate and House bills that may make it more difficult for the EPA to review and regulate risks from chemicals contained in articles. Under current TSCA, the EPA has used its authority under

section 5 to establish notification requirements for new uses of a chemical for which the EPA has concerns, including chemicals in imported articles. Section 5 does not require the EPA to make any particular exposure or hazard finding to use this authority, presumably since the function of these significant new use rules is simply to allow the EPA to review, and regulate as necessary, new uses of existing chemicals on the same basis as new chemicals. The Senate bill imposes a new requirement: the EPA must first find the notification requirement for the article is warranted based on "the reasonable potential for exposure through the article or category of articles." This new requirement may make it harder for the EPA to require notification for uses that are not currently foreseen. Even for currently envisioned uses, it may generate litigation over an EPA finding that the potential for exposure through an article or category of articles is "reasonable". The House bill exempts from regulation all "replacement parts designed prior to" the publication of a risk management rule, unless the replacement parts "contribute significantly to the identified risk." This provision would make it more difficult for the EPA to define the scope of regulations given the likely challenges of determining when particular replacement parts were designed.

Enforcement Improvements

While the Administration's Principles do not discuss civil and criminal enforcement of TSCA, the Administration supports the decision to include provisions in the Senate bill that would strengthen civil and criminal enforcement authorities. We look forward to continuing to work with Congress on these provisions.

Federal-State Relationship

The EPA's limited ability to regulate under TSCA has encouraged states to step in, resulting in varying chemical regulations across the country. Assuming the flaws in TSCA that have prevented effective federal action are addressed in reform legislation, the Administration supports an approach to preemption that provides a consistent regulatory regime for industry while allowing appropriate additional actions by the states. These comments are intended to note provisions that could benefit from drafting changes to reflect Congress's presumed intent, as well as provisions that could result in permanent preemption of state actions to address risks not addressed by federal regulation.

The Administration supports Congress's intent to preserve existing state laws like California's Proposition 65, and other state environmental laws related to the protection of air and water, and to waste. Respecting the preservation of such laws, both the Senate and House bills would benefit from further work to reflect the drafters' intent. For example, the Senate bill should better reflect its apparent intent to preserve state regulations adopted prior to August 1, 2015, not merely to enforce actions initiated prior to August 1, 2015. Similarly, the House bill should clarify that it is wholly preserving the identified laws, not just State efforts "to continue to enforce" those laws, and also that any state requirement enacted under a law that was in effect on August 31, 2003, is saved from preemption, even if the specific requirement is promulgated after the date of the TSCA Modernization Act.

The House bill should also clarify the scope of potential preemption of state environmental laws that "actually conflict[]" with an EPA "action or determination." While two

laws might be said to actually conflict if they impose incompatible obligations or one purports to abrogate the other, it is far less clear when a state law could be said to be in actual conflict with an EPA determination that is not an action, or with an EPA action that does not impose requirements.

Respecting the preservation of state laws adopted under the authority of federal law, the Administration supports the Senate bill's clarification of the types of state laws that are intended to receive such protection from preemption. Specifically, the Senate bill makes clear that this protection also extends to laws that a state adopts using its own legal authority, but that are nonetheless authorized under federal law, or adopted to satisfy or obtain authorization or approval under federal law. This clarification furthers a common sense objective: to ensure that TSCA actions do not block the purposes of the many other federal environmental statutes (e.g., the Clean Air Act) that are implemented through a system of cooperative federalism. The Senate bill's clarification is also consistent with evidence of original Congressional intent, found in TSCA's legislative history.

Furthermore, the Administration supports an approach in which any preemption resulting from a completed EPA safety assessment or risk management rule is appropriately limited to the particular risks that the agency actually considered in the scope of that assessment or rulemaking. The Administration prefers the Senate bill's clarity on this issue. On a related issue, the House bill, which does not require an affirmative safety determination for new chemicals, nonetheless would lead to preemption of state regulation for all uses of a new chemical substance identified in a pre-manufacture notification, if the agency took action merely to address a subset of those uses.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 3/8/2016 4:30:17 PM
To: Berol, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a227f36ca9ee4eeb98a95cb22058de43-DBerol]; Grant, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec6104b72cab42ba9b1e1da67d4288ae-Grant, Brian]; Schmit, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7077ecbac4914a00ad465398f92bbe78-Schmit, Ryan]
Subject: RE: Section 4 TA
Attachments: Re: Last section 4 thing; Sen. Markey TSCA TA request - more on section 4, SEnate 4(a); FW: URGENT FW: Sen. Markey TSCA TA - Senate section 4; Sen. Markey TSCA TA - Senate section 4

Brian,
Here's what I found – let me know if more search needed, can look back through last year. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Berol, David
Sent: Monday, March 07, 2016 3:59 PM
To: Grant, Brian <Grant.Brian@epa.gov>; Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Schmit, Ryan <schmit.ryan@epa.gov>
Subject: RE: Section 4 TA

Here's what I have in my files.

David Berol
U.S. EPA Office of General Counsel
202-564-6873
berol.david@epa.gov

From: Grant, Brian
Sent: Monday, March 07, 2016 3:56 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Schmit, Ryan <schmit.ryan@epa.gov>; Berol, David <Berol.David@epa.gov>
Subject: Section 4 TA

Hey guys. I believe we sent Michal some section 4 ta over the last few weeks -- not the TA on sec 4(f) specifically, but more general TA on a sec 4 draft we got from her. Does that ring a bell and if so can you circulate? Thanks.

Brian Grant
Office of General Counsel
202-564-5503

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/20/2016 10:58:23 PM
To: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Subject: Re: Last section 4 thing

Michal,
We did not consider costs in the decision to invoke 4f. Thanks,
Sven

On Feb 19, 2016, at 6:20 PM, "Freedhoff, Michal (Markey)" <Michal_Freedhoff@markey.senate.gov> wrote:

Not for the weekend. The question of whether when you used 4(f) for formaldehyde, did you include cost considerations.

Thanks!

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/25/2016 1:59:33 PM
To: Distefano, Nichole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31d32a3a3a9e4591b5fdfc3eb96e8b78-Distefano,]
Subject: Fwd: Administration Views Letter on TSCA Reform Bills
Attachments: TSCA Reform Views.Boxer.pdf; ATT00001.htm

Boxer's views letter

From: "Kaiser, Sven-Erik" <Kaiser.Sven-Erik@epa.gov>
Date: January 20, 2016 at 7:11:26 PM EST
To: "'bettina_poirier@epw.senate.gov'" <bettina_poirier@epw.senate.gov>
Subject: Administration Views Letter on TSCA Reform Bills

Bettina,
Please see attached and let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/10/2016 3:50:44 PM
To: Cleland-Hamnett, Wendy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b84439fcdf02426abd539d8bb6c9ef6f-Cleland-Hamnett, Wendy]; Schmit, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7077ecbac4914a00ad465398f92bbe78-Schmit, Ryan]; Flattery, Priscilla [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf3936418d3944f6a520c8fdba5cfdef-Flattery, Priscilla]; Mclean, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=869a9152d655420594d8f94a966b8892-KMCLEAN]; Grant, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec6104b72cab42ba9b1e1da67d4288ae-Grant, Brian]; Berol, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a227f36ca9ee4eeb98a95cb22058de43-DBerol]
Subject: RE: NEW - HEC TSCA TA Request on Nomenclature/Mixtures
Attachments: Markey.TSCA TA. Enzyme Nomenclature.docx; Markey.TSCA TA.Nomenclature.docx; Interpretation of Nomenclature Provisions -- OGC draft.docx; RE: SEPW Committee Report - Issues with language on TSCA inventory

Past nomenclature/mixtures TA attached – could also help with Jean Fruci's nomenclature request. There was additional material from last July - I can send that along if needed. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Cleland-Hamnett, Wendy
Sent: Wednesday, February 10, 2016 10:30 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Jones, Jim <Jones.Jim@epa.gov>; Schmit, Ryan <schmit.ryan@epa.gov>; Flattery, Priscilla <Flattery.Priscilla@epa.gov>; Mclean, Kevin <Mclean.Kevin@epa.gov>; Grant, Brian <Grant.Brian@epa.gov>; Berol, David <Berol.David@epa.gov>; Distefano, Nichole <DiStefano.Nichole@epa.gov>
Subject: RE: NEW - HEC TSCA TA Request on Mixtures

Should be able to recycle some previous TA?

Wendy Cleland-Hamnett
Director
Office of Pollution Prevention & Toxics
Office of Chemical Safety and Pollution Prevention
202 564-3810 (O) 202 564-0575 (F)
cleland-hamnett.wendy@epa.gov

From: Kaiser, Sven-Erik
Sent: Wednesday, February 10, 2016 10:18 AM
To: Jones, Jim <Jones.Jim@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Schmit, Ryan <schmit.ryan@epa.gov>; Flattery, Priscilla <Flattery.Priscilla@epa.gov>; Mclean, Kevin <Mclean.Kevin@epa.gov>; Grant,

Brian <Grant.Brian@epa.gov>; Berol, David <Berol.David@epa.gov>; Distefano, Nichole <DiStefano.Nichole@epa.gov>
Subject: NEW - HEC TSCA TA Request on Mixtures

TSCA Team,
Jerry Couri requests technical assistance on "statutory mixture" and nomenclature. Please see the exchange below and let me know if any questions about the request. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Wednesday, February 10, 2016 9:58 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: HEC TSCA TA Request on Mixtures

I am not looking for the 40 page definition. I want "statutory mnixture" within the nomeclature context.

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Kaiser, Sven-Erik
Sent: Wednesday, February 10, 2016 9:53 AM
To: Couri, Jerry
Subject: HEC TSCA TA Request on Mixtures

Jerry – got your message requesting TA on the statutory definition of mixtures EPA uses in a TSCA regulatory context. Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Base text from Senate Report is in bold.

EPA interpretation and TA is in italics.

***

(3) NOMENCLATURE.—

(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

EPA interprets this as a requirement to continue its current practice of allowing Class 2 chemical substances to be named and listed as discrete entries on the TSCA Inventory. EPA believes it would retain technical discretion to ensure that Class 2 chemical naming is done correctly.

There are three kinds of Class 2 chemical substances. The first kind are "UVCB substances" (i.e., Unknown or Variable Composition, Complex Reaction Products and Biological Materials). UVCB naming consists of assigning a single chemical substance name to a particular product rather than attempting to separately identify the formula and structure of each molecule constituting the product. For example, "Corn, Steep Liquor" is reported as a single chemical substance, with a single CAS number 66071-94-1.

The two other kinds of Class 2 chemical substances are:

(a) Substances defined in terms of a single molecular formula, but without distinguishing between multiple possible structural isomers (e.g., the multiple structural isomers of xylene: C_8H_{10})

(b) Substances defined in terms of a single molecular formula (e.g., $AlCe_3NiS_7$,), without defining molecular structure at all.

Commented [GB1]: Judgment call as to whether to retain this additional information or go with just the first paragraph..

(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

EPA interprets this as a requirement to continue its current practice of naming a certain subset of UVCB substances according to the particular naming convention set forth in the above-cited documents. In general terms, the substances at issue are the soap-like derivatives of certain fats and oils.

(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

(I) cement, Portland, chemicals, CAS No. 65997– 15–1;

(II) cement, alumina, chemicals, CAS No. 65997–16–2;

(III) glass, oxide, chemicals, CAS No. 65997–17– 3;

(IV) frits, chemicals, CAS No. 65997–18–4;

(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

The TSCA Inventory contains detailed descriptions of what categories of substances fall within the scope of the above listed CAS numbers. In general terms, whether these listings cover a substance depends on both the constituents of the substance and on whether the substance was manufactured in the course of making cements, glasses, frits, steel, or ceramics. EPA interprets this language as a statutory ratification of the scopes of these particular UVCB listings, as listed in the TSCA Inventory, in a manner consistent with appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a).

The drafting of this section could be improved in certain respects. First, it could be written to provide that the list of (I) through (VI) is an exclusive list, unless there is intent to ratify the scope of some other (unstated) descriptions found on the TSCA Inventory or elsewhere.

While EPA can interpret the phrase "all components of categories that are considered to be statutory mixtures," the phrasing is awkward and it could be improved to reduce the chance of confusion. The following would be clearer: "all substances described by the following category listings, when manufactured as described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a)."

(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature conventions, the Administrator shall—

(I) maintain the nomenclature conventions for substances; and

(II) develop new guidance that—

(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

The scope of this provision is determined by the extent of existing guidance allowing for multiple nomenclature conventions. EPA is not aware of any such existing EPA guidance.

(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

EPA is not currently aware of any chemical substance that is listed multiple times on the TSCA inventory, so it does not expect that this subparagraph would be operative. In the event such multiple listings were identified, EPA would likely delete the duplicate listing(s), obviating the need to develop guidance pursuant to this provision.

***

[PAGE * MERGEFORMAT]

Message

From: Widawsky, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6ECD0FCBEBB4A59A34D9D1EE85CC7A5-WIDAWSKY, DAVID]
Sent: 6/26/2015 7:50:35 PM
To: Flattery, Priscilla [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf3936418d3944f6a520c8fdba5cfdef-Flattery, Priscilla]
CC: Williamson, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b1209cc553b4cbe9a59f3e47dc0a312-TrWillia]; Wallace, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb92a9d14cc84b99a9049627ee2b0e48-Wallace, Ryan]; Cleland-Hamnett, Wendy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b84439fcdf02426abd539d8bb6c9ef6f-Cleland-Hamnett, Wendy]; Berol, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a227f36ca9ee4eeb98a95cb22058de43-DBerol]; Grant, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec6104b72cab42ba9b1e1da67d4288ae-Grant, Brian]; Kaiser, Sven-Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac78d3704ba94edbbd0da970921271ff-SKAISER]; Christian, Myrta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=207ad12497b04bcf8e80a0024b35a18a-MChris02]
Subject: RE: SEPW Committee Report - Issues with language on TSCA inventory
Attachments: CRPT-114srpt67.pdf; S.697 Vitter.pdf

Thanks to Ryan for catching this; the committee language is very much at odds with our experts' analysis of the implications of the bill language. To help explain the problems and disconnects, I'm going to first append our initial concerns with the bill language (which we forwarded these concerns on March 19, 2015, and I've clarified them, below). Then, I've copied the language from the committee report and indicate where they diverge - often dramatically - from the concerns we've raised. Hope this helps, in some way.

If the language goes forward as currently written, it is going to create extreme costs to doing our business, as well as introduce unmanageable and simply unworkable complications into our chemical safety mission.

Our previous comments:

Overarching comments.

- TSCA has always been based on CAS nomenclature conventions. That level of detail is appropriate in a bill. Creating or adopting additional conventions - which are based on different underlying methods and approach - is a recipe for problems that are unlikely to ever be solved (explained in more detail below).
- Additional specifics on nomenclature conventions, especially as they apply to certain specific chemicals, are not appropriate in a bill, we think. Nomenclature is dynamic and evolves. Any specific nomenclature issues that may come up (e.g., with emerging chemicals) would be more appropriately handled through guidance and/or regulations.

(3) NOMENCLATURE.-

(A) IN GENERAL.-In carrying out paragraph (1), the Administrator shall-

(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

This is good.

(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of

the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a); and

The SDA system is still applicable in certain cases, and in those cases, it is consistent with CAS/TSCA nomenclature. It is important to note that we have viewed this SDA system more as SDA guidance to their members and not as a separate/different nomenclature convention. So, while this language could be viewed to be generally ok, there is a potential problem with having this language in the bill. Some in industry have in the past interpreted guidance such as SDA's as being more broadly applicable to other classes of chemicals than what it was originally intended for. This has resulted in confusion in the past and can result in Section 5 reporting and compliance issues for both industry and EPA. *Therefore, if this language does remain in the bill and become law, and if it becomes an open-ended interpretation problem, we would not be able to fix it through guidance or regulations.*

(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation-

(I) cement, Portland, chemicals, CAS No. 65997-15-1;
(II) cement, alumina, chemicals, CAS No. 65997-16-2;
(III) glass, oxide, chemicals, CAS No. 65997-17-3;
(IV) frits, chemicals, CAS No. 6 65997-18-4;
(V) steel manufacture, chemicals, CAS No. 65997-19-5; and
(VI) ceramic materials and wares, chemicals, CAS No. 66402-68-4.

This language is problematic. Statutory mixtures are a handful of listings reported to the initial Inventory reporting rule and listed on the original Inventory, ***largely in error.*** With the absence of analytical data in the original reports, it wasn't immediately apparent that these handful of chemicals were not individual chemicals but rather were mixtures. *Having them on the Inventory has caused confusion and problems over the years regarding Section 5 reporting.* Our draft Inventory clarification rule on statutory mixtures from several years ago was intended to fix these problems, but the rule was never proposed. A more current problem associated with some of these listings is newer interpretations from some in industry that they are much broader than what they were originally intended to represent when they were first reported to the initial Inventory. For example, the ceramics listing was report in the late 1970s to cover substances like porcelain (used in things like porcelain sinks). Ceramics are now a very broad class of materials, some of which are much more sophisticated and complex, and we know that industry is not reporting some of these materials under Section 5 because they claim that they are covered by the ceramics listing and therefore are already on the Inventory. It is important to note that there are others in industry that are (and have been) reporting their new substances under Section 5, and not claiming that they are covered by one of the statutory mixtures listings.

(B) MULTIPLE NOMENCLATURE CONVENTIONS.-

(i) IN GENERAL.-If an existing guidance allows for multiple nomenclature conventions, the Administrator shall-

(I) maintain the nomenclature conventions for substances; and

The language saying that "if an existing guidance allows for multiple conventions" is problematic. We have always really had only one nomenclature convention (CAS), and maintaining that provides clarity, consistency, and transparency. The proposed language is vague (What existing guidance? Under what circumstance would this happen?). More importantly, multiple nomenclature conventions would be problematic - **period**. It's important to note that nomenclature conventions (including CAS) are

dynamic and evolve over time, as new chemicals are created all the time. Because of this, we have been and are able to seek and obtain input from experts in industry and elsewhere when a nomenclature issue is raised or anticipated (e.g., for more complex and/or emerging chemicals), and such input has been and can be considered when CAS nomenclature conventions are updated, especially for TSCA purposes. A past example is petroleum streams, and a current example is nanotubes.

(II) develop new guidance that-

(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

Having multiple conventions is highly problematic. The language is not particularly clear but is still speaking to the issue of multiple nomenclature conventions (and how to deal with such a situation. We've always used one nomenclature convention (CAS), which is extremely well-documented, well-understand, and the most definitive nomenclature system available. We should continue to use one system. Establishing equivalencies between conventions (language under "aa") would be necessary in such situations but could be extremely hard to do (the handful of conventions that exist now are apples and oranges in terms of how they approach chemical composition and structure). Moreover, if there is language in the bill that appears to allow multiple conventions, different industries could start writing their own conventions, resulting in many, and EPA would apparently be expected not only to consider/adopt all of them, but also to maintain them and provide equivalencies. This is simply not going to work.

The CAS nomenclature convention includes unique CAS names and unique CAS numbers. These are analogous to people's formal names and social security numbers (although people names aren't unique but SSNs are). An analogous situation to allowing multiple nomenclature conventions under TSCA would be like the IRS allowing people to use on tax forms either their formal names and social security numbers (like is required now) or their nicknames (the few other nomenclature conventions in existence include names that are often more incomplete and/or generic than CAS names and don't include a unique number). Again, it just won't work or meet our need to define and/or recognize unique Inventory listings for the purposes of implementing TSCA.

(ii) MULTIPLE CAS NUMBERS.-For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

This is overstated as a concern and "problem" it is trying to fix is not at all common. The language refers to situations where some in industry think that there are multiple Inventory listings for the same chemical. With >85,000 chemical on the Inventory, it is possible that this ***might*** be happening, but we think it would be pretty rare. We have asked industry on a few occasions, when it's been raised, to provide specific examples, but have received none. There are lots of inventory listings for chemicals that are very similar, but for the purpose of TSCA, are still different (and should be defined as different). It's hard to get this across to industry when many listings are CBI, and generic names might look like they are the same chemical. If industry would provide examples, and if there really are multiple listings for one chemical, we can collapse them into one. We don't want multiple listings either.

Committee Report Language (pg. 19 and 20)

Under TSCA, numerous nomenclature conventions exist that
may prevent the efficient distribution of chemicals into commerce.
It is the intent of the Committee that the provisions of section 10
related to nomenclature will resolve these issues by requiring the
Administrator to develop new guidance that will establish equivalency
between these conventions, while preserving certain nomenclature
approaches that have significant value.
Trying to reconcile different nomenclature conventions to determine equivalence is actually more likely to invite confusion and prevent "the efficient distribution of chemicals into commerce." The CAS system is robust, long-used, widely accepted, and the standard by which we should continue to work (see comments on 3(B)(i)I and 3(B)(i)II, above). Additional nomenclature conventions do not provide value to clarity, transparency, or consistency under TSCA.

It will also permit
any chemical substance appearing multiple times, each with a different
Chemical Abstract Service (CAS) number, to be treated by
the Agency as a single chemical substance. This will help prevent
duplicative safety assessments and determinations by ensuring
that substantially equivalent chemicals are considered at the same time, as appropriate.
Our experience has been that either stakeholders are not fully understanding that different chemicals with similar names are, in fact, different chemicals, and may have properties that are different and relevant to regulatory criteria (see comment on 3(B)iii, above.) When EPA has requested claimants of this "problem" to provide specific examples, EPA received none.

The Committee believes this approach will
also help enhance EPA's ability to evaluate substances from new
sources against existing substances for equivalence, enabling similar
substances to rely on the Inventory listing of an existing substance.s
Same concern as above: [Trying to reconcile different nomenclature conventions to determine equivalence is actually more likely to invite confusion and prevent "the efficient distribution of chemicals into commerce." The CAS system is robust, long-used, widely accepted, and the standard by which we should continue to work (see comments on 3(B)(i)I and 3(B)(i)II, above). Additional nomenclature conventions do not provide value to clarity, transparency, or consistency under TSCA.]

The Committee also intends that EPA's guidance should address
those instances where multiple, different substances share
the same CAS number. These substances may have different hazard
profiles, but these distinguishing characteristics are not transparent
to the public and stakeholders.
Same concern as above: [Our experience has been that either stakeholders are not fully understanding that different chemicals with similar names are, in fact, different chemicals, and may have properties that are different and relevant to regulatory criteria (see comment on 3(B)iii, above.) When EPA has requested claimants of this "problem" to provide specific examples, EPA received none.]

Current TSCA provides EPA the authority to list a category of
substances on the inventory, rather than list individually each
chemical substance within a category. S. 697 maintains this authority
to ensure that minor modification or variations in the formulation
or structure of a chemical substance that have insignificant
health or environmental consequences would not be automatically
subject to the notification requirements of section 5.
Retaining the authority to list categories is important to EPA. But, instead, the legislative language codifies a set of categories that were initially erroneous. Furthermore, fixing these categories in legislative language fails to address the fact that chemicals and chemicals categories evolve over time, which a great deal of collaborative effort ongoing to

make sure they are consistent within the scientific field of chemical nomenclature (see comments on 3(A)ii and 3(A)iii, above).

The Committee
believes that EPA's current policy of not requiring notification
for variations in naturally-occurring substances or mixtures
should generally be continued.

TSCA requires a chemical substance to be listed on the TSCA Inventory
before it is commercialized. However, TSCA does not require
EPA on an ongoing basis to identify which substances on the
Inventory are actually in commerce. With approximately 84,000
substances now on the Inventory-but less than 8,000 chemical
substances reported under the EPA's Chemical Data Reporting
Rule as being produced in volumes above the rule's reporting
threshold-it is important that EPA (and the American public)
have a better picture of what substances are in actual commerce
at any given time. The failure to identify active substances has created
confusion.
S. 697 addresses this problem by requiring that EPA categorize
the substances on the TSCA Inventory as active or inactive. The
categorization process is critical to the success of EPA's
prioritization process, which focuses primarily on active substances.
Importantly, the section does not authorize EPA to remove substances
from the Inventory. Instead, manufacturers or processors
who wish to designate an inactive substance as active have an obligation
to notify EPA. Manufacturers of an inactive substance may
return the substance to the active inventory with a simple notification
to EPA, at which time the substance becomes subject to the
prioritization screening, safety assessment and determination processes.

[We were not asked to comment upon this earlier (in March). The idea that all entries currently in the TSCA Inventory can be categorized as either active or inactive is logistically nearly unworkable, because original submitters often bear little, passing, or no resemblance to those currently engaged in production, manufacturing, processing, or importing chemicals covered by TSCA. Identifying, tracking, and engaging entities who might would assert the need for an Inventory entry to be characterized as active could be a logistical nightmare and consume vast amounts of EPA resources. Moreover, because chemicals on the TSCA inventory are produced in batches that may serve as inventory for more than one year, being able to consistently track those chemicals as active would be extremely difficult (even if the language covers a 10-year span). It is hard to see how this proposed language improves the efficiency of prioritization or reduces confusion about what is in the marketplace. A much more straightforward approach would be to simply expand the scope of chemicals covered by CDR.]

****

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widawsky.david@epa.gov
****

Check out EPA's pollution prevention initiatives:
>> www.epa.gov/p2
>> www.epa.gov/greenchemistry

>> www.epa.gov/SaferChoice
>> www.E3.gov
>> www.epa.gov/epp

From: Flattery, Priscilla
Sent: Friday, June 26, 2015 10:35 AM
To: Widawsky, David
Subject: FW: SEPW Committee Report

Is this something you can look at in Tracy's absence.

Priscilla Flattery
Chief of Staff, OPPT
202-564-2718

From: Flattery, Priscilla
Sent: Friday, June 26, 2015 10:30 AM
To: Williamson, Tracy
Cc: Widawsky, David; Tillman, Thomas
Subject: FW: SEPW Committee Report

Tracy - Can you take a look at this and get back to me on Monday. Thanks.

Priscilla Flattery
Chief of Staff, OPPT
202-564-2718

From: Wallace, Ryan
Sent: Friday, June 26, 2015 10:16 AM
To: Flattery, Priscilla; Cleland-Hamnett, Wendy
Cc: Berol, David; Grant, Brian; Mclean, Kevin; Kaiser, Sven-Erik
Subject: SEPW Committee Report

Priscilla,

The SEPW Committee Report includes some discussion of the nomenclature provisions of the Bill (middle of page 20 in the attached report). I don't fully understand the implications of these provisions, but I recall that Tracy's assessment of them was not quite as positive as they have characterized here. I think it might be a good idea to have someone take a look at the comments in the report to see how they line up with our assessment. I've also attached the Bill version that was voted out of committee for reference.

Thanks,
Ryan

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/26/2016 3:52:24 PM
To: Schmit, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7077ecbac4914a00ad465398f92bbe78-Schmit, Ryan]; Grant, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec6104b72cab42ba9b1e1da67d4288ae-Grant, Brian]
Subject: Sen. Markey TSCA Reform Questions
Attachments: question on conditions of use and preemption; Sen. Markey Followup Inquiry on TSCA Section 26 and First 10 Workplan Chemicals; Section 5 vs 6

Ryan and Brian – I'm checking on best way to handle Michal's TSCA reform questions (attached). At one point I thought that a call might be more efficient, I understand that Jim Jones prefers that we respond in writing. I suspect that draft responses may already exist for some of these. Thoughts on proceeding? Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Sent: 7/26/2016 8:36:59 PM
To: Kaiser, Sven-Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac78d3704ba94edbbd0da970921271ff-SKAISER]
Subject: question on conditions of use and preemption

Flag: Follow up

Sven

Something that I've been talking to a bunch of people about relates to the nature of EPA's obligation to assess all conditions of use associated with a chemical substance as part of a risk evaluation. It was this perceived obligation that led to the development of the partial RE language, so I understand EPA's general take – but I have some questions about how EPA interprets the final bill language, and how EPA would expect this to intersect with 18a preemption. While this isn't a time-sensitive request, it does bear directly on the RE and prioritization rulemakings, and I'm guessing your team is also asking itself these same questions. Thanks.

I'm pasting below some of the hey references to conditions of use in the bill and in caps, my read on these – first question – is EPA's read consistent with mine (and if not, what am I missing)?:

(4) The term 'conditions of use' means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. IMPLIED – EPA SHOULD SURVEY/COLLECT THE KNOWN UNIVERSE OF USES FOR A SUBSTANCE

(i) HIGH-PRIORITY SUBSTANCES.—The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator. MY READ – EPA CAN DEEM SOMETHING TO BE A HIGH PRIORITY CHEMICAL IF ANY USE MEETS THE "MAY PRESENT" THRESHOLD. LESS CLEAR TO ME - EPA COULD ALSO DETERMINE, AT THIS STAGE IN THE PROCESS, THAT SOME USES DO NOT MEET THIS THRESHOLD, BECAUSE OF THE HIGHLIGHTED LANGUAGE BELOW

(A) ESTABLISHMENT OF PROCESS.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall establish, by rule, a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time. The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.

(4) RISK EVALUATION PROCESS AND DEADLINES.—

(i) (A) IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use. IMPLIED – EPA HAS TO DO A RISK EVALUATION ON ALL USES OF THE CHEMICAL. LESS CLEAR – COULD EPA ARGUE THAT IT ONLY HAS TO DO A FULL RISK EVALUATION ON ANY USE THAT MET THE "MAY PRESENT" THRESHOLD WHEN THE CHEMICAL WAS DESIGNATED A HIGH PRIORITY CHEMICAL?

(F) REQUIREMENTS.—In conducting a risk evaluation under this subsection, the Administrator shall—

(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;

(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;

(iii) not consider costs or other nonrisk factors;

(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and I

(v) describe the weight of the scientific evidence for the identified hazard and exposure. - IMPLIED – THIS LIST OF REQUIREMENTS APPLIES TO ALL USES OF THE CHEMICAL. LESS CLEAR – COULD EPA ARGUE THAT IT ONLY HAS TO DO A FULL RISK EVALUATION TO WHICH THESE REQUIREMENTS APPLYON ANY USE THAT MET THE "MAY PRESENT" THRESHOLD WHEN THE CHEMICAL WAS DESIGNATED A HIGH PRIORITY CHEMICAL?

"(D) SCOPE.—The Administrator shall, not later than 6 months after the initiation of a risk evaluation, publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations **the Administrator expects to consider** …" THIS LANGUAGE SEEMS TO STATE THAT EPA DOES HAVE THE DISCRETION TO ONLY LOOK AT SOME OF THESE CONSIDERATIONS, INCLUDING CONDITIONS OF USE, AS PART OF A FULL RISK EVALUATION.

So the rest of my questions are as follows:

1) Does EPA believe it has to do a full risk evaluation on all conditions of use? In that case, would any use that EPA did not find posed an unreasonable risk be part of a "no unreasonable risk determination" for that chemical, and would those also be subject to 18a preemption?
2) Does EPA believe it has to CONSIDER all conditions of use, decide when it is prioritizing the chemical which uses meet the threshold for an RE and which do not, and document that as part of prioritization? In that case, would the uses that did not meet the threshold for an RE need to be deemed "low priority chemical conditions of use" or otherwise just not be in the RE, not subject to any final agency action (and thus not subject to any preemption)?
3) Does EPA believe it has to CONSIDER all conditions of use as part of scoping the RE, and that it also has to note which ones are getting a full RE in the scope and describe the reasons why it is not giving a full RE to some uses? In that case, for the uses that are not getting a full RE, would EPA be able to make a "no unreasonable risk" determination (and thus subject these uses to 18a preemption) even though EPA chose not to fully review them, or could these uses just receive no final agency action regulatory treatment and thus not be subject to 18a preemption?
4) Are there other alternatives that I haven't considered that better describe EPA's interpretation of the language?

18(a)(1) (B) CHEMICAL SUBSTANCES FOUND NOT TO PRESENT AN UNREASONABLE RISK OR RESTRICTED.—A statute, criminal penalty, or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

(i) for which the determination described in section 6(i)(1) is made, consistent with the scope of the risk evaluation under section (6)(b)(4)(D); or

(ii) for which a final rule is promulgated under section 6(a), after the effective date of the rule issued under section 6(a) for the chemical substance, consistent with the scope of the risk evaluation under section (6)(b)(4)(D).

c) SCOPE OF PREEMPTION.—Federal preemption under subsections (a) and (b) of statutes, criminal penalties, and administrative actions applicable to specific chemical substances shall apply only to—

(1) with respect to subsection (a)(1)(A), the chemical substances or category of chemical substances subject to a rule, order, or consent agreement under section 4, 5, or 6;

(2) with respect to subsection (b), the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in the scope of the risk evaluation pursuant to section 6(b)(4)(D);

(3) with respect to subsection (a)(1)(B), the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to section 6(a) or 6(i)(1); or

(4) with respect to subsection (a)(1)(C), the uses of such chemical substances that the Administrator has specified as significant new uses and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.

Director of Oversight & Investigations
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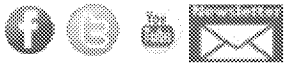
Connect with Senator Markey



Message

From: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Sent: 9/9/2016 5:56:18 PM
To: Kaiser, Sven-Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac78d3704ba94edbbd0da970921271ff-SKAISER]
Subject: Section 5 vs 6

Flag: Follow up

Hi Sven

I have some questions about the interplay between sections 5 and 6.

1) If EPA initiates a risk evaluation on a chemical substance, can it legally decide that it no longer wishes to do one (for whatever reason) and stop doing so? Is the answer to this question different for a first 10 WP chemical as compared to a prioritized chemical?
2) If EPA a) initiates a risk evaluation on a chemical substance in order to find out whether the substance posed an unreasonable risk under the conditions of use, b) simultaneously or subsequently issues a SNUR requiring notification for all or some of the conditions of use of the substance, and c) receives a notification from a manufacturer subject to the SNUR, could EPA determine that the use intended by the manufacturer posed an unreasonable risk under section 5 before the risk evaluation under section 6 was completed? In other words, would EPA's authority under section 5 be limited by the existence of an incomplete section 6 risk evaluation?

Thanks
Michal

Michal Ilana Freedhoff, Ph.D.
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Connect with Senator Markey

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 8/25/2016 6:31:20 PM
To: Kaiser, Sven-Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac78d3704ba94edbbd0da970921271ff-SKAISER]
Subject: Sen. Markey Followup Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

Flag: Follow up

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Friday, August 12, 2016 11:57 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Re: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

Thanks very much - so you don't read anything in the act as saying you can only do RES on substances that have been designated high priority? How does that work in terms of the various timeframes and notice and comment periods required for prioritization and scoping of RE?

Could you, for example
Designate the flame retardants on the WP as a category/ies in the next few months
At the same time, designate a separate category of FRS (does category designation require notice/comment)?
When prioritization and RE rules go final, designate the second FR category as high priority, comply with all deadlines/scoping, and finish the two RES at the same time and do rulemaking at the same time?

Thanks!

Michal Ilana Freedhoff, Ph.D.
Director of Oversight and Investigations
Office of Senator Edward J. Markey (D-MA)

From: Kaiser, Sven-Erik
Sent: Friday, August 12, 2016 11:51 AM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

Michal,
This responds to the questions on TSCA section 26 and the first 10 chemicals.

Question:
First 10 Workplan chemicals and categories
What if there were some chemically analogous substances on the WP, but some chemically analogous substances that were NOT on the WP. Could the latter non-WP chemicals be evaluated/regulated as part of a first 10 WP group? ie do ALL the chemicals in the category need to be on the WP in order to be in the first 10 list?

First 10 Workplan chemicals and preemption
Say the scenario I have below works. You have 1 chemical on the WP, and you create a category that ropes in an additional 12 non-WP chemicals that are structurally analogous. What happens to those 12 non-WP chemicals if they hitch a ride on one of the first 10 WP REs by way of preemption? are they exempt from pause? If not, since they are not high-prioritized, what are they preemption-wise?

EPA Response: Based on our analysis of the statute to date, we are doubtful that TSCA authorizes EPA to establish a category (consisting of both Workplan chemical substances and non-Workplan chemical substances) and to then deem that category as one of the 10 Workplan chemical substances. Here is our reasoning:

- Section 26(c) establishes a rule of statutory construction for understanding how the rest of TSCA operates with respect to a category: "any reference in this Act to a chemical substance . . . (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance . . . in such category)"

- Turning to section 6(b)(2)(A), the statute specifies that in order to be among the initial 10, a chemical substance must be "drawn from the 2014 update of the TSCA Work Plan."

- Applying the rule of statutory construction from section 26(c) to the command in section 6(b)(2)(A), this seems to transform the requirement that a chemical substance be drawn from the Workplan into a requirement that "each chemical substance" in the category be drawn from the Workplan.

But EPA need not fold analogous non-Workplan chemical substances into a broader Workplan chemical category in order to proceed expeditiously with these non-Workplan analogues. TSCA gives EPA the flexibility to start a risk evaluation on a chemical substance that has not been identified as a Workplan chemical substance, designated as a high priority substance, or requested by industry. Thus, EPA could simply start risk evaluations on certain non-Workplan chemical substances at the same time that it starts risk evaluations on the analogous Workplan chemical substances. With respect to pause preemption, there would be no pause preemption for the non-Workplan analogues unless and until EPA designated them as high priority substances under section 6(b)(1)(B)(i).

For example, EPA could use its category authority to create two categories. The first would be a set of chemically analogous substances, all of which were drawn from the Workplan. The second would be a set of further chemically analogous substances, not drawn from the Workplan. EPA could identify the first category under section 6(b)(2)(A) and start a risk evaluation accordingly. EPA would not identify the second category under section 6(b)(2)(A), but could nonetheless start a risk evaluation on it, in tandem with the first category.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, July 19, 2016 3:18 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

And, actually, a second followup here – say the scenario I have below works. You have 1 chemical on the WP, and you create a category that ropes in an additional 12 non-WP chemicals that are structurally analogous. What happens to those 12 non-WP chemicals if they hitch a ride on one of the first 10 WP REs by way of preemption? are they exempt from pause? If not, since they are not high-prioritized, what are they preemption-wise?

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations

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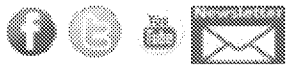

From: Freedhoff, Michal (Markey)
Sent: Tuesday, July 19, 2016 2:49 PM
To: 'Kaiser, Sven-Erik'
Subject: RE: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

As a follow-up question -- what if there were some chemically analogous substances on the WP, but some chemically analogous substances that were NOT on the WP. Could the latter non-WP chemicals be evaluated/regulated as part of a first 10 WP group? ie do ALL the chemicals in the category need to be on the WP in order to be in the first 10 list?

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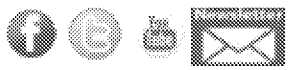

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Tuesday, July 19, 2016 12:17 PM
To: Freedhoff, Michal (Markey)
Subject: Sen. Markey Inquiry on TSCA Section 26 and First 10 Workplan Chemicals

Michal,
This responds to the inquiry on using TSCA section 26 for the first 10 Workplan chemicals. You ask whether EPA believes it would be legally defensible to deem a category of chemically analogous Workplan chemicals to be a single chemical substance, for purposes of section 6(b)(2)(A) (EPA to commence risk evaluations for 10 chemical substances within 180 days of enactment). We believe this would be a legally defensible exercise of EPA's authority under 26(c).

EPA has broad discretion under section 26(c) to define chemical categories, including based on similar uses and similar chemical properties. With respect to such categories, section 26(c) establishes a general rule of construction that applies throughout the whole Act: "any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category." Thus, one of the 10 chemical substances referenced in 6(b)(2)(A) could be actually be a category that EPA established under 26(c).

The question you raise is not beyond debate, but we believe ours is the better reading of the statute. Congress knew about the existence of 26(c) at the time TSCA was amended to add 6(b)(2)(A), and yet did not limit 26(c) to prevent it from being applied to 6(b)(2)(A). We therefore believe that the stronger implication is that Congress did not intend to modify 26(c) so that it applies more narrowly in the context of 6(b)(2)(A). Furthermore, in terms of section 6 implementation, a category of chemically analogous Workplan chemicals would take the functional place of a single chemical substance – EPA could practicably issue a single risk evaluation for that category and address any unreasonable risk by a single rule.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
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From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Thursday, July 07, 2016 3:22 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TSCA question followup

HI Sven

In the call we had a couple weeks ago, it sounded like OGC hadn't yet made a determination about whether you can use the section 26 category authority for the first 10 WPs (ie, group flame retardants or pigments even though they are not necessarily grouped on the WP itself). Has that been figured out yet?

I'm getting increasing numbers of requests for EJM to weigh in on various chemicals and am trying to sort out whether it makes any sense for him to do so.

Thanks
Michal

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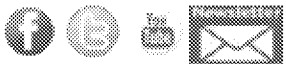

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 9/13/2016 4:04:06 PM
To: Parsons, Doug [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0a745542b2e4fa894e877ccf8b83957-Parsons, Doug]
Subject: Sen. Markey - 12 PCB questions
Attachments: Markey.PCB.Set 1.docx; Markey.PCB.Set 2.1.docx; PCB questions

Doug, attached are the two sets of responses sent so far. Still missing 4, 9, 10. The full set from the incoming message is attached for reference. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
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Message

From: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Sent: 7/19/2016 9:59:14 PM
To: Kaiser, Sven-Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac78d3704ba94edbbd0da970921271ff-SKAISER]
CC: Bogdanoff, Alec (Markey) [Alec_Bogdanoff@markey.senate.gov]
Subject: PCB questions
Attachments: 07-09-15EDW15659.pdf

Flag: Follow up

Sven

Here are a bunch of questions for your team – thanks. It would be great to get your sense of how long these will take to respond to. It is fine with me if you respond to them as you get each one answered - no need to wait til they are all done if you think some will take longer than others. I've attached our MASK Act, which I know you've looked at before, for your reference.

Thanks
michal

1. Do contractors that are remediating PCB-containing building materials like those that might be found in schools require special accreditation the way asbestos-workers do? if not, should they, or is the removal of such materials less complicated to do? what about inspectors? Title II of TSCA goes on at some length about the types of courses and certifications that are required by asbestos contractors and inspectors – is something like this needed (or is it already in the 6e rules) for PCBS?

2. Title II of TSCA defines ASBESTOS-CONTAINING MATERIAL.—The term ''asbestos- containing material'' means any material which contains more than 1 percent asbestos by weight. I know you are in the midst of re-drafting your PCB rules. Would a definition of PCB-CONTAINING MATERIAL which I drew from your 1998 PCB regulation make sense, or are there different/more items I should be considering?

"The term polychlorinated biphenyl-containing material means 1) a fluorescent light ballast that contains more than 50 parts per million in the insulating material which fills the space between the functioning parts of the ballast and its outer metal covering, 2) a nonliquid material containing polychlorinated biphenyls at concentrations of more than 50 parts per million but less than 500 parts per million [QUESTION – WOULD THIS CAPTURE CAULK AND PAINT, AND WHY THE 500 PPM MAX?] AND 3) DO I NEED TO WORRY ABOUT PCB-CONTAINING ELECTRICAL EQUIPMENT IN SCHOOLS OR OTHER THINGS BESIDES WHAT IS LISTED IN THIS DRAFT DEFINITION?,

3. Title II of TSCA contains the following definition: (12) RESPONSE ACTION.—The term ''response action'' means methods that protect human health and the environment from asbestos-containing material material. Such methods include methods described in chapters 3 and 5 of the Environmental Protection Agency's ''Guidance for Controlling Asbestos-Containing Materials in Buildings.'' Are these the analogous PCB documents listed below? If so, can you pls send the right URLs (all the links are broken), and if not, can you pls send the right materials?

EPA and Federal Partners

- Fact Sheets for Schools and Teachers about PCB-Contaminated Caulk from EPA provides information about PCBs in caulk used in some buildings, including schools, in the 1950s through the 1970s and offers suggestions on what to say to children about PCBs to encourage proper precautions. The website includes:
  - Fact Sheet for Schools: PCBs in Caulk School Checklist (PDF) (1pp, 106KB)

- PCB-Containing Fluorescent Light Ballasts in School Buildings: A Guide for School Administrators and Maintenance Personnelfrom EPA provides information on the risks posed by PCBs in light ballasts, how to properly handle and dispose of these items and how to properly retrofit school lighting fixtures to remove potential PCB hazards.
- PCBs in Caulk in Older Buildings on the EPA website offers background information, steps to minimize exposure, testing methods and a schools information kit.

4. Title II of TSCA refers to "least burdensome" in several places . Would it be better to delete these references?

5. Title II of TSCA tells EPA to prescribe transportation and disposal regulations for asbestos-containing waste. I am assuming that your 6(e) regs (and any revisions thereto) would cover this for PCBs, right?

6. Title II of TSCA requires warning labels to be placed in maintenance areas when inspections discover asbestos-containing materials. It is not clear to me that a similar label should be required for PCB-containing materials in schools given the different nature of these materials. Does EPA have a technical view?

7. Title II of TSCA says you can only update the asbestos removal guidance through rulemaking. Is it typical to require guidance updates to be done by rule, and if not, would it make sense to delete that requirement in this case?

8. Title II of TSCA describes an inspection standard and methodology that must be met for asbestos: Either a scanning electron microscope or a transmission electron microscope shall be used to determine the ambient interior concentration. In the absence of reliable measurements, the ambient exterior concentration shall be deemed to be—

> (A) less than 0.003 fibers per cubic centimeter if a scanning electron microscope is used, and
> (B) less than 0.005 fibers per cubic centimeter if a transmission electron microscope is used.

Does EPA still believe that this is the right methodology and standard? If not, what is?
Is there an analogous standard and methodology for PCBs and if so what is it?

9. As I gather from other TA, the Asbestos Trust Fund won't really exist anymore soon:

"The asbestos loan program is a direct loan program managed under the Credit Reform Act of 1990 (CRA). The issuance of new asbestos loans under the program officially ended in 1993. Subsequently, all remaining loan activity since 1993 has occurred for managing loan repayment/collection activities in accordance with the CRA and Debt Collection Act requirements. The Credit Reform Act of 1990 precludes Agencies from repurposing funds for other needs. All asbestos loan related funds under the loan program are managed in accordance with the CRA, which specifically identifies how to manage collections received. Because FY 2016 serves as the final subsidy closing re-estimate year for the asbestos direct loan program, all of the remaining balances related to the Act requirements (including the $32,189.20 amount) are expected to be zeroed out prior to September 30, 2016 in close-out transactions at the end FY 2016. Although the funds may look available, they are not. The funds are tied to the Asbestos loan program, which is managed under the Credit Reform Act of 1990. The CRA identifies the process for final closing re-estimates. The final Asbestos loan closing re-estimate is in process and will sweep all of the account balances to Treasury prior to September 30, 2016."

But the statutory text does not talk about loans. It talks about grants. I'm confused about your TA as well as what we might need to do legislatively to reverse the outcome you've described above, or specify that the program is managed under the credit reform act of 1990. Can you please help me understand the statutory basis for your TA above as well as what a statutory remedy might be?

For purposes of this sub- section, a ''violation'' means a failure to comply with respect to a single school building. The court shall order that any civil penalty collected under this subsection be used by the local educational agency for purposes of complying with this title. Any portion of a civil penalty remaining unspent after compliance by a local edu- cational agency is completed shall be deposited into the Asbestos Trust Fund established by section 5 of the Asbestos Hazard Emer- gency Response Act of 1986.

10. The MASK Act authorizes $10 mill/year for enforcement of asbestos requirements. If the bill was drafted to expand to PCBs as well, would EPA need more resources, and if so, how much?

11. Does the asbestos ombudsman still exist at EPA, and does the role work as envisioned? Should it be expanded to include PCBS?

12. Title II of TSCA required EPA to do a one-time study of where asbestos is in public bldgs.. The MASK Act requires these to be redone every 10 years. Would there be a benefit to a similar PCB study?

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114TH CONGRESS
1ST SESSION

S. _____

To protect the people of the United States from asbestos exposure by requiring the disclosure of asbestos and asbestos-containing materials in homes to buyers, tenants, and remodelers, updating information to be collected and published regarding the manufacture, sale, import, and distribution of asbestos and asbestos-containing products in the United States, reestablishing Federal oversight of asbestos professional training and building management programs, and improving public awareness and understanding of asbestos hazards.

IN THE SENATE OF THE UNITED STATES

Mr. MARKEY introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To protect the people of the United States from asbestos exposure by requiring the disclosure of asbestos and asbestos-containing materials in homes to buyers, tenants, and remodelers, updating information to be collected and published regarding the manufacture, sale, import, and distribution of asbestos and asbestos-containing products in the United States, reestablishing Federal oversight of asbestos professional training and building management programs, and improving public awareness and understanding of asbestos hazards.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Maximizing Asbestos Safety and Knowledge Act of 2015" or the "MASK Act".

SEC. 2. ESTABLISHMENT OF ASBESTOS-CONTAINING PRODUCT DATABASE.

(a) IN GENERAL.—The Asbestos Information Act of 1988 (15 U.S.C. 2607 note; Public Law 100–577) is amended—

(1) in section 4—

(A) by redesignating paragraphs (3) through (7) as paragraphs (4) through (8), respectively; and

(B) by inserting after paragraph (2) the following:

"(3) ASBESTOS-CONTAINING PRODUCT.—The term 'asbestos-containing product' means any product (including any part) to which asbestos is deliberately or knowingly added or in which asbestos is deliberately used or knowingly present in any concentration.";

(2) in section 2, by inserting "(referred to in this Act as the 'Administrator')" after "Adminis-

trator of the Environmental Protection Agency''; and

(3) by adding at the end the following:

''SEC. 5. ASBESTOS-CONTAINING PRODUCT DATABASE.

''(a) IN GENERAL.—Using funds otherwise made available to the Administrator, the Administrator shall, in accordance with this section, establish and maintain a database of asbestos-containing products (referred to in this Act as the 'database') that is—

''(1) publicly available;

''(2) searchable; and

''(3) accessible through the website of the Administrator.

''(b) SUBMISSION OF DETAILED IMPLEMENTATION PLAN TO CONGRESS.—

''(1) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Administrator shall submit to the appropriate congressional committees a detailed plan for establishing and maintaining the database, including plans for the operation, content, maintenance, and functionality of the database.

''(2) INTEGRATION.—The plan described in paragraph (1) shall detail the integration of the

database into the overall information technology improvement objectives and plans of the Administrator.

"(3) IMPLEMENTATION.—The plan described in paragraph (1) shall include—

"(A) a detailed implementation schedule for the database; and

"(B) plans for a public awareness campaign conducted by the Administrator to increase awareness of the database.

"(c) DATE OF INITIAL AVAILABILITY.—Not later than 180 days after the date on which the Administrator submits the plan under subsection (b)(1), the Administrator shall establish the database.

"(d) SUBMISSION OF INFORMATION ON ASBESTOS-CONTAINING PRODUCTS.—

"(1) IN GENERAL.—Beginning on the date that is 270 days after the date of enactment of this section, and not less frequently than annually thereafter, any person who manufactured, processed, distributed, sold, imported, transported, or stored an asbestos-containing product in the immediately preceding calendar year shall submit to the Administrator a written report, in a form to be determined by the Administrator, containing information suffi-

cient to identify the characteristics and location of the asbestos-containing products.

"(2) CONTENTS.—The report under paragraph (1) shall include—

"(A) the type or class of asbestos-containing product;

"(B) the manufacturer of the asbestos-containing product;

"(C) any applicable import history of the asbestos-containing product;

"(D) the name and street address of any location accessible by the public in which the person has reasonable knowledge that the asbestos-containing product has been present within the immediately preceding calendar year; and

"(E) any additional information the Administrator determines is appropriate to enable consumers and workers to avoid exposure to asbestos-containing products.

"(e) ORGANIZATION OF DATABASE.—The Administrator shall—

"(1) categorize the information available on the database—

"(A) in a manner consistent with the public interest; and

"(B) in such manner as the Administrator determines will facilitate easy use by consumers; and

"(2) ensure, to the maximum extent practicable, that the database is sortable and accessible by—

"(A) the date on which information is submitted for inclusion in the database;

"(B) the name of the asbestos-containing product;

"(C) the model name;

"(D) the name of the manufacturer;

"(E) the name of the importer, if applicable;

"(F) the name of the reporting person;

"(G) the name and street address of any location in which an asbestos-containing product is reported to have been present; and

"(H) any other element the Administrator considers to be in the public interest.

"SEC. 6. PENALTIES.

"(a) IN GENERAL.—Any person who knowingly manufactured, processed, distributed, sold, imported, trans-

ported, or stored an asbestos-containing product in the immediately preceding calendar year and who did not submit a report to the Administrator under section 5 shall be liable for a civil penalty of $10,000 for each day after the deadline under section 5(d)(1) the report has not been submitted.

"(b) FALSE OR INACCURATE INFORMATION.—Any person who knowingly provides false or inaccurate information in a report under section 5 or who knowingly fails to provide information required in a report under section 5 shall be liable for a civil penalty of $10,000 for each violation of this paragraph.".

(b) GOVERNMENT ACCOUNTABILITY OFFICE REPORT.—Not later than 2 years after the Administrator of the Environmental Protection Agency establishes the database of asbestos-containing products under section 5(a) of the Asbestos Information Act of 1988 (15 U.S.C. 2607 note; Public Law 100–577) (referred to in this subsection as the "database"), the Comptroller General of the United States shall submit to the appropriate congressional committees a report that contains—

(1) an analysis of the utility of the database, including—

(A) an assessment of the extent of use of the database by consumers, including—

(i) whether the database is accessed by a broad range of the public; and

(ii) whether consumers find the database to be useful; and

(B) efforts by the Administrator to inform the public about the database;

(2) recommendations for measures to increase use of the database by consumers; and

(3) recommendations for measures to further reduce the harm caused by exposure to asbestos, including bans on the importation and use of asbestos-containing products.

SEC. 3. DISCLOSURE OF ASBESTOS INFORMATION ON TRANSFER OF REAL PROPERTY AND APPLICATION FOR BUILDING PERMITS.

(a) IN GENERAL.—Title II of the Toxic Substances Control Act (15 U.S.C. 2641 et seq.) is amended by adding at the end the following:

"SEC. 217. DISCLOSURE OF ASBESTOS INFORMATION ON TRANSFER OF REAL PROPERTY.

"(a) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator, in consultation with the Secretary of Housing and Urban Development and the Secretary of Health and Human Services, shall issue regulations under this section requiring

the disclosure by the seller or lessor of the existence of any known asbestos or asbestos-containing material in a residential or commercial property that is offered for sale or lease.

"(b) REQUIREMENTS.—The regulations issued under subsection (a) shall require that, before the purchaser or lessee is obligated under any contract to purchase or lease a residential or commercial property, the seller or lessor shall—

"(1) disclose to the purchaser or lessee the presence of any known asbestos or asbestos-containing material in or on the property;

"(2) provide to the purchaser or lessee—

"(A) an asbestos information pamphlet required under subsection (c); and

"(B) any asbestos inspection available to the seller or lessor; and

"(3) permit the purchaser a 10-day period (or a period of time mutually agreed upon by all parties) to conduct an inspection for the presence of asbestos or asbestos-containing material.

"(c) ASBESTOS INFORMATION PAMPHLET.—The Administrator shall develop, publish, make available on the website of the Environmental Protection Agency, and peri-

odically revise an asbestos information pamphlet, which shall—

"(1) contain information regarding the health risks associated with exposure to asbestos;

"(2) contain information regarding the presence of asbestos and asbestos-containing materials, including asbestos-containing building material, in residential and commercial properties in the United States;

"(3) describe the risks of asbestos exposure to occupants of buildings, including the risks of renovation or remodeling in buildings that may have asbestos or asbestos-containing material;

"(4) explain that an inspection for asbestos is recommended prior to purchase, lease, renovation, or demolition of residential or commercial property;

"(5) disclose that certain State and local laws may impose additional requirements related to asbestos or asbestos-containing material, and provide contact information for appropriate Federal, State, and local agencies within each State that can provide information about applicable laws and available resources, including those on websites maintained by the Administrator; and

"(6) provide such other information about environmental hazards associated with residential or commercial property as the Administrator determines is appropriate.

"(d) ASBESTOS WARNING STATEMENT IN CONTRACTS FOR PURCHASE OR SALE.—

"(1) IN GENERAL.—The regulations issued under subsection (a) shall require that each contract for the purchase or sale of residential or commercial property shall contain—

"(A) an asbestos warning statement; and

"(B) a statement signed by the purchaser that the purchaser—

"(i) has read and understands the asbestos warning statement;

"(ii) has received the asbestos information pamphlet under subsection (c); and

"(iii) has received a 10-day opportunity (or a period of time mutually agreed upon by all parties) to conduct an inspection for the presence of asbestos hazards before becoming obligated under the contract to purchase the property.

"(2) CONTENTS.—The asbestos warning statement required under paragraph (1)(A) shall contain

the following text printed in bold-face type, no smaller than 12-point font, on a separate page attached to the contract:

"'Each purchaser of any interest in real property on which a residential or commercial building is located is notified that the property may contain asbestos or asbestos-containing materials. Asbestos was used extensively in construction in the United States between 1900 and 1980. Asbestos is a hazardous air pollutant associated with several serious health problems for anyone exposed to it. Asbestos that is in good condition and left undisturbed is unlikely to present a health risk; however, if asbestos is damaged or disturbed (which may happen as the building ages and during construction, renovation, and demolition), the asbestos fibers can become airborne, be inhaled, and cause serious health risks (including asbestosis, lung cancer, and mesothelioma). Accordingly, a risk assessment or inspection for possible asbestos hazards is recommended prior to purchase of any building, and buildings known to have asbestos or asbestos-containing materials should be inspected periodically for signs of asbestos damage or deterioration and repaired as necessary by profes-

sional inspectors and contractors who are accredited by the Environmental Protection Agency.'.

"(3) COMPLIANCE ASSURANCE.—In the case of an agent entering into a contract on behalf of a seller or lessor for the purpose of selling or leasing a residential or commercial property, the regulations issued under subsection (a) shall require the agent to ensure compliance with the requirements of this section.

"(e) ENFORCEMENT.—

"(1) PROHIBITED ACT.—It shall be unlawful for any person to fail or refuse to comply with any rule or order issued under this section.

"(2) CIVIL PENALTY.—Any person who violates paragraph (1) shall be subject to a civil penalty in an amount not to exceed $10,000 for each violation.

"(3) ACTION BY ADMINISTRATOR.—The Administrator may take action as necessary to enjoin a violation of a regulation issued under subsection (a).

"(4) PURCHASER AND LESSEE REMEDIES.—A person who knowingly violates a regulation issued under subsection (a) shall be jointly and severally liable to the purchaser or lessee in an amount equal to 3 times the amount of damages incurred by the purchaser or lessee as a result of the violation.

"(5) COSTS.—In a civil action for damages under paragraph (4), the court may award to the party commencing the action court costs, reasonable attorney fees, and expert witness fees, if that party prevails in the action.

"(f) NO EFFECT ON CONTRACTS AND LIENS.—Nothing in this section—

"(1) affects the validity of any sale or contract for the purchase and sale of residential or commercial real property or any loan, loan agreement, mortgage, or lien made or arising in connection with a mortgage loan; or

"(2) creates a defect in title.

"SEC. 218. DISCLOSURE OF ASBESTOS INFORMATION ON APPLICATION FOR BUILDING PERMITS.

"(a) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator, in consultation with the Secretary of Housing and Urban Development, shall issue regulations under this section for the disclosure of asbestos or asbestos-containing material in any residential or commercial property on any application for a building permit to make any addition, alteration, repair, replacement, or demolition to or of the residential or commercial property.

"(b) REQUIREMENTS.—The regulations issued under subsection (a) shall require that, before a building permit described in subsection (a) is issued, the State or unit of local government authorized to issue the permit shall provide to the applicant an asbestos information pamphlet required under section 217(c).

"(c) APPLICATIONS FOR BUILDING PERMITS.—The regulations issued under subsection (a) shall require that each application for a building permit to make any addition, alteration, repair, replacement, or demolition to or of any residential or commercial property shall contain—

"(1) an asbestos warning statement under subsection (d); and

"(2) a statement signed by the applicant that the applicant—

"(A) has read and understands the asbestos warning statement;

"(B) has received an asbestos information pamphlet under section 217(c); and

"(C) certifies that, if asbestos or asbestos-containing material is known to be or is discovered in or on the property during the performance of work under the building permit, all work shall cease until the work can be continued by a professional contractor accredited by

the appropriate authority in the jurisdiction to handle asbestos safely.

"(d) ASBESTOS WARNING STATEMENT.—The asbestos warning statement required under subsection (c)(1) shall contain the following text printed in bold-face type, no smaller than 12-point font, on a separate page attached to the building permit application:

" 'Every applicant for a building permit for a major improvement to or demolition of real property on which a residential or commercial building is located is notified that such property may contain asbestos or asbestos-containing materials. Asbestos was used extensively in construction in the United States between 1900 and 1980. Asbestos is a hazardous air pollutant associated with several serious health problems for anyone exposed to it. Asbestos that is in good condition and left undisturbed is unlikely to present a health risk; however, if asbestos is damaged or disturbed (which may happen as the building ages and during construction, renovation, and demolition), the asbestos fibers can become airborne, be inhaled, and cause serious health risks (including asbestosis, lung cancer, and mesothelioma). Accordingly, a risk assessment or inspection for possible asbestos hazards is recommended prior to undertaking major improvements to or demolition of any building. Major improvements to or demolition of

any building known to have asbestos or asbestos-containing materials should be performed by professional inspectors and contractors who are accredited by the Environmental Protection Agency.'.''.

(b) NO PREEMPTION OF CERTAIN STATE AND LOCAL LAWS.—Consistent with section 209 of the Toxic Substances Control Act (15 U.S.C. 2649), nothing in this section or the amendments made by this section—

(1) preempts a State or local law that establishes more stringent requirements than the requirements established under this section or the amendments made by this section; and

(2) precludes or prevents a State or unit of local government from adopting or enforcing standards or limitations that are more stringent than those required under this Act.

SEC. 4. EPA OVERSIGHT OF ASBESTOS ACCREDITATION AND MANAGEMENT PROGRAMS.

(a) IN GENERAL.—Title II of the Toxic Substances Control Act is amended—

(1) in section 202 (15 U.S.C. 2642)—

(A) in paragraph (7)—

(i) in subparagraph (A), by striking the period at the end and inserting a semicolon; and

(ii) in subparagraph (B), by striking ", and" and inserting "; and";

(B) in paragraph (10), by striking "any residential apartment building of fewer than 10 units" and inserting "any residential building";

(C) by redesignating paragraphs (11) through (14) as paragraphs (12) through (15), respectively; and

(D) by inserting after paragraph (10) the following:

"(11) RESIDENTIAL BUILDING.—The term 'residential building' means any real property improvement of not less than 1 and not more than 4 residential dwelling units, units in residential cooperatives, or condominium units, including the limited common elements allocated to the exclusive use of the condominium unit.";

(2) in section 203 (15 U.S.C. 2643), by striking subsection (m) and inserting the following:

"(m) CERTIFICATION, PERIODIC REVIEW, AND OVERSIGHT.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Maximizing Asbestos Safety and Knowledge Act of 2015, and after an op-

portunity for public notice and comment, the Administrator shall—

"(A) revise regulations issued by the Administrator regarding waivers described in section 763.98 of title 40, Code of Federal Regulations, to ensure that the regulations are at least as stringent as the requirements under this section and section 204; and

"(B) review asbestos management in each State and any waiver that was issued to a State before the date of enactment of the Maximizing Asbestos Safety and Knowledge Act of 2015—

"(i) to ensure that the asbestos management program of each State is at least as stringent as the regulations contained in subpart E of part 763 of title 40, Code of Federal Regulations (as in effect on March 1, 2015); and

"(ii) to ensure that each State has made adequate efforts to comply with the requirements under this title.

"(2) CONTENTS OF REGULATIONS.—The revised regulations issued under paragraph (1) shall—

"(A) require that each State, not later than 1 year after the date of enactment of the

Maximizing Asbestos Safety and Knowledge Act of 2015 and every 10 years thereafter, shall submit to the Administrator—

"(i) a copy of the asbestos management program of the State that demonstrates that the management program implemented by the State is at least as stringent as the regulations contained in subpart E of part 763 of title 40, Code of Federal Regulations (as in effect on March 1, 2015); and

"(ii)(I) written notification that the State has not requested a waiver in accordance with the regulations revised under paragraph (1);

"(II) a copy of the asbestos accreditation plan of the State that—

"(aa) includes the date on which the program was adopted and implemented;

"(bb) demonstrates that the accreditation program implemented by the State is at least as stringent as the regulations contained in subpart E of part 763 of title 40, Code of

Federal Regulations (as in effect on March 1, 2015); and

"(cc) if applicable, includes the date on which the State received formal approval from the Administrator, the Director of the National Institute of Standards and Technology, or other appropriate official for the contractor and laboratory accreditation plan under section 206; or

"(III) a verification that the State has adopted and implemented a model accreditation plan in accordance with the Asbestos Model Accreditation Plan issued by the Administrator and described in Appendix C of subpart E of part 763 of title 40, Code of Federal Regulations; and

"(B) reestablish Federal oversight of asbestos accreditation plans and management programs to ensure that each State addresses asbestos hazards with plans that are at least as stringent as the requirements under this section and section 204.

"(3) CERTIFICATION BY ADMINISTRATOR.—On receipt of the asbestos accreditation plan and the

management program submitted in accordance with paragraph (2), the Administrator shall—

"(A) assess the asbestos inspection plan and management program of each State under this section;

"(B) make a determination regarding whether the programs referred to in subparagraph (A) meet the requirements under this section and section 204;

"(C) issue to the State the determination made under subparagraph (B); and

"(D) if the Administrator determines that the plans or programs referred to in subparagraph (A) do not meet the requirements under this section and section 204—

"(i) describe the aspects of the plans or programs that are inadequate;

"(ii) describe the facts upon which the Administrator relied to make the finding under this subparagraph; and

"(iii) describe the corrective action that is required and the timeframe in which the State must take the corrective action.

"(4) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of the Maximizing Asbestos Safety and Knowledge Act of 2015 and annually thereafter, the Administrator shall submit to Congress a report that describes—

"(A) the certifications of accreditation plans under paragraph (3), including—

"(i) a description of the States that adopted the model accreditation plan described in paragraph (2)(A)(ii)(III); and

"(ii) a description of the States that received a certification from the Administrator under paragraph (3) for the accreditation plan;

"(B) any applications for a waiver submitted by a State and reviewed and approved by the Administrator; and

"(C) any actions that the Administrator has taken to ensure compliance with this title in each State that—

"(i) submitted a written notification in accordance with paragraph (2)(A)(ii)(I); or

"(ii) did not receive a certification under paragraph (3).";

(3) in section 205(e) (15 U.S.C. 2645(e)), by adding at the end the following:

"(3) WRITTEN STATUS REPORT.—Not less frequently than once every 10 years, the Governor of each State shall submit to the Administrator a report on the status of management plan submissions and deferral requests by local educational agencies in the State, which shall—

"(A) be made available to local educational agencies in the State; and

"(B) contain a list that includes, with respect to the period covered by the report—

"(i) each local educational agency within the jurisdiction of the State;

"(ii) each local educational agency the management plan of which was submitted and not disapproved;

"(iii) each local educational agency the management plan of which—

"(I) was submitted and disapproved; and

"(II) remains disapproved;

"(iv) each local educational agency that failed to submit a management plan; and

"(v) any emergency actions taken by the State pursuant to emergency authority under section 208 to protect human health or the environment from asbestos hazards, and the outcomes of those emergency actions.";

(4) in section 206(a) (15 U.S.C. 2646(a)), by striking "or in a public or commercial building" each place it appears and inserting "or in a public, commercial, or residential building"; and

(5) in section 207 (15 U.S.C. 2647)—

(A) in subsection (g), by striking "in a school, public or commercial building" each place it appears and inserting "in a school, public, commercial, or residential building"; and

(B) by adding at the end the following:

"(h) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out enforcement activities under this title not less than $10,000,000 for each fiscal year.

"(i) COMPLIANCE BY STATES.—In order to receive funds to carry out activities under this title, a State shall be in compliance with the requirements of this title, as determined by the Administrator.".

(b) NO PREEMPTION OF CERTAIN STATE AND LOCAL LAWS.—Consistent with section 209 of the Toxic Substances Control Act (15 U.S.C. 2649), nothing in this section or the amendments made by this section—

(1) preempts a State or local law that establishes more stringent requirements than the requirements established under this section or the amendments made by this section; and

(2) precludes or prevents a State or unit of local government from adopting or enforcing standards or limitations that are more stringent than those required under this Act.

(c) CONFORMING AMENDMENTS.—Section 302 of the Toxic Substances Control Act (15 U.S.C. 2662) is amended—

(1) in paragraph (2), by striking "by section 202(8)" and inserting "in section 202"; and

(2) in paragraph (4), by striking "by section 202(13)" and inserting "in section 202".

SEC. 5. RESEARCH AND EDUCATION.

(a) EPA STUDY OF ASBESTOS-CONTAINING MATERIAL IN PUBLIC BUILDINGS.—Section 213 of the Toxic Substances Control Act (15 U.S.C. 2653) is amended—

(1) in the matter preceding paragraph (1), by striking "Within 360 after the date of the enactment

of this title'' and inserting ''Not later than 2 years after the date of enactment of the Maximizing Asbestos Safety and Knowledge Act of 2015 and every 10 years thereafter'';

(2) in paragraph (1), by striking ''public and commercial buildings'' and inserting ''public, commercial, or residential buildings'';

(3) in paragraph (2), by striking ''commercial buildings'' and inserting ''public or commercial buildings'';

(4) in paragraph (3), by striking ''public and commercial buildings'' and inserting ''public or commercial buildings''; and

(5) in paragraph (5), by striking ''public and commercial buildings'' and inserting ''public or commercial buildings''.

(b) RESEARCH.—The Administrator of the Environmental Protection Agency (referred to in this section as the ''Administrator''), in cooperation with other Federal agencies, including the Director of the National Institutes of Health, the Director of the National Science Foundation, the Director of the National Institute for Occupational Safety and Health, the Administrator of the Agency for Toxic Substances and Disease Registry, the Executive Director of the Consumer Product Safety Commission, the

Director of the National Institute of Environmental Health Sciences, the Director of the National Institute of Standards and Technology, the Assistant Secretary of Labor for Occupational Safety and Health, and the Director of the United States Geological Survey, shall conduct research to improve understanding of exposure risks to asbestos fibers and other elongate mineral particles.

(c) GRANTS FOR ASBESTOS RESEARCH.—

(1) DEFINITIONS.—In this subsection:

(A) QUALIFIED ENTITY.—The term "qualified entity" means—

(i) a unit of State or local government;

(ii) a nonprofit or for-profit organization; and

(iii) an institution of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001)).

(B) QUALIFIED RESEARCH PROJECT.—The term "qualified research project" means—

(i) a scientific research project designed to advance or achieve the strategic research goals and objectives described in the document entitled "Asbestos Fibers and Other Elongate Mineral Particles:

State of the Science and Roadmap for Research'', published by the Director of the National Institute for Occupational Safety and Health in April 2011; and

(ii) a project that the Administrator, in consultation with other Federal agencies, determines to be a priority for preventing, treating, or curing an asbestos-related disease.

(2) ESTABLISHMENT OF GRANT PROGRAM.—The Administrator shall carry out a grant program to make grants to qualified entities for qualified research projects.

(3) APPLICATIONS.—A qualified entity seeking a grant under this subsection shall submit to the Administrator an application at such time, in such manner, and containing such information as the Administrator may reasonably require.

(4) LENGTH OF GRANT PROJECT.—

(A) IN GENERAL.—A grant awarded under this subsection shall be for a term of 3 years.

(B) RENEWAL.—A qualified entity receiving a grant under this subsection may renew the grant by submitting to the Administrator a renewal application at such time, in such man-

ner, and containing such information as the Administrator may reasonably require.

(5) REPORTS.—

(A) REPORTS BY GRANT RECIPIENTS.—A qualified entity receiving a grant under this subsection shall submit to the Administrator a report at such time, in such manner, and containing such information as the Administrator may reasonably require.

(B) REPORT TO CONGRESS.—Not less frequently than annually, the Administrator shall submit to Congress a report that contains all information submitted to the Administrator by qualified entities under subparagraph (A) during the immediately preceding year.

(6) AUTHORITY OF ADMINISTRATOR.—The Administrator may issue such guidelines, rules, regulations, and procedures as may be necessary to carry out this section.

(7) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $1,000,000 for each of fiscal years 2017 through 2022.

(d) PUBLICATION OF INFORMATION.—The Administrator, in consultation with the Secretary of Housing and

Urban Development and the Secretary of Health and Human Services, shall—

(1) review, revise as appropriate, publish, and make available on the website of the Environmental Protection Agency updated information for each of the documents entitled—

(A) "Guidance for Controlling Asbestos-Containing Material in Buildings", published in March 1986;

(B) "Asbestos Fact Book", published in February 1985;

(C) "Asbestos in the Home", published in August 1982; and

(D) "Asbestos in Your Home", published in September 1990; and

(2) maintain a website available to the public, which may be the same website as the website required under section 3(d) of the Asbestos Information Act of 1988 (15 U.S.C. 2607 note; Public Law 100–577), that—

(A) serves as a national clearinghouse for asbestos hazards; and

(B) collects, evaluates, and disseminates current information on—

(i) assessment and reduction of asbestos hazards;

(ii) adverse health effects;

(iii) sources of exposure;

(iv) detection and risk assessment methods;

(v) environmental hazards abatement; and

(vi) cleanup standards.

SEC. 6. REPORTS TO CONGRESS.

Not less frequently than once every 2 years, the Administrator of the Environmental Protection Agency shall submit to Congress a report that—

(1) describes the progress of the Administrator in implementing asbestos hazard evaluation and reduction activities described in this Act and the amendments made by this Act;

(2) contains recommendations for legislative and administrative initiatives to further reduce asbestos hazards; and

(3) describes the results of research carried out under this Act and the amendments made by this Act.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 10/13/2015 9:16:54 PM
To: 'Couri, Jerry' [JerryCouri@mail.house.gov]
Subject: RE: HEC Inquiry on IPC Meeting
Attachments: IPC letter 10-13-15.pdf

Jerry,
Thanks for the reminder. Attached is a letter from EPA to IPC following up on the points raised at the Aug 11, 2105 meeting. A similar letter went to Honda. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Friday, October 02, 2015 3:18 PM
To: Kaiser, Sven-Erik
Subject: RE: HEC Inquiry on IPC Meeting

Sorry to bother on this rainy day.

Anything more you can share on this and what may be happening?

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Wednesday, September 16, 2015 10:52 AM
To: Kaiser, Sven-Erik
Subject: Anything you can share about..

What came from the August 11, 2015 meeting between IPC , Honda, and Jim Jones? I thought I heard there was a commitment by Mr. Jones to look into the section 8 reporting issue they raised and get back to them in a couple of weeks.

Gerald S. Couri
Senior Environmental Policy Advisor | Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn Building | 202.226.9603 (direct)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

John W. Mitchell
President & CEO
IPC - Association Connecting Electronics Industries
3000 Lakeside Drive, Suite 105N
Bannockburn, IL 60015

Dear Mr. Mitchell:

Thank you for your letter in follow-up to our in-person meeting this summer. As you know, my staff has been meeting with various industry representatives over the past year to listen to your concerns about the byproduct reporting issues. The Agency acknowledges these concerns, and will continue to strive for the reporting requirements that both inform EPA's important work to protect human health and the environment, and minimize burden on industry.

EPA has several activities underway to simplify the next Chemical Data Reporting (CDR) period of June 1, 2016 to September 30, 2016. For example, the Agency is making continual improvements to the CDR reporting process and instructions. Subsequent to the 2012 CDR period, we received specific suggestions for improvement from the American Chemistry Council (ACC) and others, and have incorporated several of these suggestions into the 2016 reporting application. Examples of new improvements to the CDR reporting application include:

- Providing notification to the user when entering chemical(s) into the CDR reporting application if the chemical(s) is/are subject to specific TSCA actions or any exemptions that impact the reporting requirements.
- Prepopulating certain fields to ease reporting burden.
- Improving navigation ability for the user when entering CBI substantiation for multiple elements.

We'd like to invite you to participate in a webinar on Wednesday, October 14th to walk through the 2016 CDR reporting application. In November, there will also be an opportunity to assist EPA in testing and to provide feedback on the new reporting application. We will provide you more information about this opportunity as we finalize the details.

In addition to updating the reporting application, we have several new guidance materials that should help to clarify many of the potentially confusing byproduct reporting scenarios that you have brought to our attention. Specifically, we will soon be posting to the CDR website three new industry-specific byproducts reporting fact sheets for: (1) Metal Mining, (2) Electric Utilities and (3) Printed Circuit Board manufacturing. These guidance documents address some

of the specific reporting scenarios you mentioned at our August 11th meeting including reporting of "spent etchant" byproduct and other complex combinations of substances.

As we mentioned during our last meeting, data on manufactured byproducts is important to EPA's efforts to protect human health and the environment. EPA uses CDR data in the following ways:

- *The production volume of a manufactured (including imported) chemical substance, and whether processed or used at the reporting site*: EPA will use these data for chemical manufacturing, processing, and use-trend analyses; and for the assessment of the effectiveness of Agency and public programs, among other uses. The on-site volumes are related to potential exposures and provide the Agency with information for exposure assessments and other data analyses.

- *The number of workers exposed, the maximum concentration of a chemical, and the physical form of a chemical:* These data elements provide exposure-related information that allows EPA to screen chemical substances based on the potential for risk in order to protect human health.

- *Whether a manufactured (including imported) chemical substance, such as a byproduct, is being recycled, remanufactured, reprocessed, or reused*: This data element provides information on the exposure pathway of chemicals within the industry.

- *Industrial processing and use data*: This data element identifies the functions of the chemical substances. The industrial function categories include the type of process or use operation, the industrial sector and the industrial function category. Processing and use information helps EPA, other agencies, and the general public to readily screen and prioritize chemicals for the purpose of identifying potential human health and environmental effects.

- *Consumer and commercial end-use exposure data:* These data are reported separately and are used to determine exposure potential based on consumer or commercial populations. These two populations are very different from each other, and the ability to distinguish uses between the two enables better exposure-based screening of the chemical substance. Additionally, within the consumer product category, submitters must report to the extent they know if the chemical is used in products intended for children. This information allows EPA and the public to better understand what is in children's products and allows the Agency to focus in on chemical risks related to children's health.

Finally, you also raised the issue of additional and potentially duplicative reporting under TRI, even when there is no chemical release. Unlike CDR, TRI does not require the reporting of the quantities of any chemical manufactured, processed or otherwise used. However, if within a calendar year a facility exceeds a reporting threshold for a chemical included on the TRI list of toxic chemicals, it must submit a Form R report whether it released any of the chemical or not, and it must include in the report information on the releases and other waste management involving the chemical (unless it meets the criteria for submission of the shorter Form A.) These

reporting requirements also apply to chemicals manufactured as a byproduct. Thus, if a facility subject to the TRI reporting requirements within a calendar year manufactures a TRI listed chemical as a byproduct in quantities that exceed the TRI reporting threshold for that chemical, the facility is required to report information on releases of that chemical to EPA's TRI Program, even if there were no releases (i.e., the releases quantity would be reported as zero). The facility is not required to report to EPA's TRI Program the quantity it manufactured as a byproduct; only that the chemical was manufactured as a byproduct. If the facility sent any of the chemical byproduct off-site to be recycled, the facility also would report to EPA's TRI Program the amount sent off-site for recycling and denote this processing information to CDR.

OPPT continues to look for further opportunities to streamline reporting between the two programs. We would note, however, that changes to the scope of CDR reporting requirements would require notice and comment rulemaking, and would not take effect until the 2020 reporting period.

Again, as always, we appreciate your input to our CDR program and we look forward to working with you as we launch the new reporting tool and head into the next reporting cycle. To find out more about the upcoming webinar and opportunity to test the CDR application, please feel free to contact Susan Sharkey of my staff, at sharkey.susan@epa.gov or 202-564-8789.

Sincerely,

James J. Jones
Assistant Administrator

cc: John Hasselmann
Fern Abrams

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 8/19/2016 5:38:14 PM
To: Cherepy, Andrea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c52459ab00fd4f0eae85c32cdc9c73dd-ACherepy]; Schmit, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7077ecbac4914a00ad465398f92bbe78-Schmit, Ryan]
CC: Parsons, Doug [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0a745542b2e4fa894e877ccf8b83957-Parsons, Doug]
Subject: Request for TSCA Fees TA history
Attachments: CBO Request on TSCA and FIFRA Fees; CBO TSCA TA Request on cost estimates for House (4-22) compared to S.697; CBO TSCA TA Request on cost estimates for House (4-22) compared to S.697; HEC TSCA TA Request on Fees; HEC TSCA TA Request on FY15 Budget; RE: Sen. Udall TSCA TA Request on User Fees; Senate TSCA TA on Appropriations and Fees; SEPW TSCA TA Fees Question; RE: TSCA Reform TA - Fee Scenarios; RE: TSCA Reform TA - Fee Scenarios; TSCA Reform TA - Fee Scenarios; CBO TA on House TSCA Bill Cost Estimates

Andrea, this responds to the request for TA on TSCA fees language. Attached are some of the most significant pieces of TA on TSCA reform. Note that there may be more detailed exchanges on specific issues, as well as TA on earlier bills, that are not included here. Please keep this close hold and also be aware that any requests to share the TA need to go through Jim Jones and OCIR. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Cherepy, Andrea
Sent: Monday, August 15, 2016 2:22 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Parsons, Doug <Parsons.Douglas@epa.gov>
Subject: request for information

Sven,

Barbara requested that I reach out to you for a copy of any and all cost-related TSCA information that was sent out as part of technical assistance. We are starting to engage our stakeholders, hold industry consultation and work on drafting the proposed Fees Rule. Anything you have would be useful.

Thank you,
Andrea

Andrea Cherepy
on detail to:
Office of Pollution Prevention & Toxics
U.S. Environmental Protection Agency
Telephone: 202 343-9317
Email: cherepy.andrea@epa.gov

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/12/2016 4:01:46 PM
To: 'Jon Sperl' [Jon.Sperl@cbo.gov]; Gross, Peter [Peter_M_Gross@omb.eop.gov]; Terris, Carol [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87abf69049c94368881e93dc19187011-cterris]
Subject: CBO Request on TSCA and FIFRA Fees
Attachments: Response to CBO on FIFRA.7.7.16.docx

Jon,
This responds to the request on pesticide program fees. Please see the attached background paper and let me know if any questions, including whether a call helpful. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Jon Sperl [mailto:Jon.Sperl@cbo.gov]
Sent: Tuesday, June 28, 2016 11:37 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Cc: Terris, Carol <Terris.Carol@epa.gov>
Subject: EPA's fee gap - services to the private sector

Dear Sven and Carol,

CBO is working on its next release of our report entitled, "Options for Reducing the Deficit." In the report, there is an option that describes the amount of revenue that could be generated from fees if fees were imposed to cover the cost of administering government regulations and services provided to the private sector. For EPA, the relevant fees are those associated with the costs the agency incurs to review/register pesticides under FIFRA/PRIA and toxic chemicals under TSCA.

TSCA
In 2013 and 2015, CBO estimated the amount of revenue that could be generated by charging fees for those chemical review services at about $60 million/year, or roughly $0.4 billion over 10 years. Since then, however, TSCA reform has been passed into law, which allows for fee collections to defray the costs of 25% of EPA's Chemical Risk Review program, but not all of it. That program was funded at $58 million in 2016, and we estimated, based on feedback from EPA, that it will need to increase in size to around $75 million to cover the new workload in TSCA reform. Thus, EPA will annually continue to spend $50-55 million per year providing services to the private sector under TSCA for which it is not reimbursed with fees.

Pesticides
In terms of pesticides, I do not have any good information at this time quantifying the extent to which EPA's current fee structure under PRIA is able to cover the agency's costs for pesticide review.

In short: In these two areas (and others if I've missed them), has EPA quantified the size of this "gap" between EPA's costs to review pesticides and chemicals and how much of that the agency is able to cover in fee collections?

Any insights you can provide—or folks you could connect me with (particularly for pesticides, as I have a pretty good sense of the TSCA side)—would be greatly appreciated.

Thanks!
Jon

Jon Sperl
Associate Analyst, Congressional Budget Office
Federal Estimates (EPA), State and Local Gov. Estimates (Energy/Environment/Other)
Ford House Office Building, Room 441-D
(202) 226-9092, jon.sperl@cbo.gov

Response to CBO on FIFRA & PRIA Fees

PRIA fees and Maintenance fees have provided between **20% - 27%** of total OPP resources as depicted by the chart below:

History of PRIA & Maintenance Fees Collected and Congressional Appropriations[1]

Fiscal Year	PRIA Fees Collected	Maintenance Fees Collected	Maintenance Fee Target	Congressional Appropriations	Fees as % of total Program resources[2]
2004	$14.7M	$25.9M	$26.0M	$131.5M	40.6/172.1 = **24%**
2005	$10.6M	$28.0M	$27.0M	$126.1M	38.6/164.7 = **23%**
2006	$13.9M	$25.7M	$27.0M	$137.9M	39.6/177.5 = **22%**
2007	$13.1M	$21.5M	$21.0M	$134.3M	34.6/168.9 = **20%**
2008	$15.8M	$22.0M	$22.0M	$133.5M	37.8/171.3 = **22%**
2009	$16.1M	$21.8M	$22.0M	$137.3M	37.9/175.2 = **22%**
2010	$18.6M	$22.1M	$22.0M	$142.8M	40.7/183.5 = **22%**
2011	$11.6M	$22.8M	$22.0M	$136.6M	34.4/171 = **20%**
2012	$15.6M	$22.0M	$22.0M	$128.3M	37.6/165.9 = **23%**
2013	$15.2M	$27.0M	$27.8M	$121.8M	42.2/164 = **26%**
2014	$16.6M	$28.6M	$27.8M	$122.1M	45.2/167.3 = **27%**
2015	$17.1M	$27.7M	$27.8M	$120.0M	44.8/164.8 = **27%**
2016			$27.8M		

PRIA and Maintenance fees for the past three years have provided roughly **34% - 35%** of expenditures as depicted below:

Registration and Registration Review/Reregistration Expenditures by OPP

	FY'13	FY'14	FY'15
Expenditures from appropriations	$94.7426M	$89.0899M	$88.6043M
Expenditures from PRIA fund	$9.8164M	$15.7036M	$15.7207M
Expenditures from maintenance fee fund	$19.9039M	$24.5895M	$22.1162M
total	**$124.4629M**	**$129.383M**	**$126.4412M**

[1] PRIA fees and Maintenance fees support OPP-only pesticide program activities while congressional appropriations support Agency-wide pesticide activities.

[2] Fees as a percentage of total program resources = (PRIA fees collected + maintenance fees collected)/ (PRIA fees collected + maintenance fees collected + congressional appropriations)

PRIA and Maintenance Fees Collected

	FY'13	FY'14	FY'15
PRIA fees collected	$15.2M	$16.6M	$17.1M
Maintenance fees collected	$27.0M	$28.6M	$27.7M
Total	**$42.2M**	**$45.2M**	**$44.8M**

Fees as a Percentage of OPP Expenditures

	FY'13	FY'14	FY'15
Fees as a % of expenditures	$42.2/$124.4629 = **34%**	$45.2/$129.383 = **35%**	$44.8/$126.4412 = **35%**

Fees as a percentage of OPP expenditures was the old way of presenting the information, but more recently the program has been using fees as a percentage of total program resources as a more accurate measure.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/17/2015 2:53:43 PM
To: 'Susanne Mehlman' [Susanne.Mehlman@cbo.gov]
Subject: CBO TA on House TSCA Bill Cost Estimates

Susanne,

This responds to your earlier questions about fees in the House TSCA bill.

1. Pre-Manufacturing Notification (PMN) fees

Under the current fee structure, EPA will collect about $1.1 million in FY2015. With the cap removed under the House bill, if EPA is able to collect fees to "defray costs" at 100 percent of the cost of administering the new chemicals program, EPA estimates collecting up to $14 million.

2. CBI Penalties

The House bill establishes new authority for EPA to assess TSCA penalties against persons who receive confidential business information pursuant to section 14(a) and then proceed to improperly use or disclose such information. Specifically, section 9(h) of the bill (Page 38, lines 18-23) amends section 15 to make "any requirement of this title" subject to civil and criminal penalties set forth in Section 16 (e.g., up to $25,000 per/day civil penalties). In addition, section 14(f) is added by the bill, to provide that "[n]o person who receives information as permitted under subsection (a) may use such information for any purpose not specified in such subsection, nor disclose such information to any person not authorized to receive such information."

3. Manufacturer Requested Assessments

We have little reliable information on which to base an estimate. The number will depend on manufacturer balancing of the potential costs and benefits of requesting an evaluation. Currently, EPA undertakes about 10 assessments a year and this could be a default figure for manufacturer requests. The actual number of industry requests will be impacted by the relatively high cost of paying 100 percent for an assessment (current EPA funded assessments can be up to $1 million) and the uncertainty of the outcome due to potential follow on risk management action (currently 50 percent of EPA assessments lead to risk management action). It seems reasonable to expect a lower amount of manufacturer requested assessments to lead to risk management action since manufacturers would be less likely to submit assessment requests where risk management action is foreseeable. Note also that the cost of risk management actions would be wholly borne by EPA and currently can cost about $1.5 million each in program costs.

This language is provided by EPA as technical assistance in response to a congressional request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any additional questions. Thanks.

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Susanne Mehlman [mailto:Susanne.Mehlman@cbo.gov]
Sent: Tuesday, June 16, 2015 10:43 AM
To: Kaiser, Sven-Erik
Subject: RE: House TSCA Bill

I am still looking over everything you sent BUT I will need more info on the fees...not sure what numbers to go with . I can assume similar levels to Senate bill.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 4/25/2016 11:58:40 PM
To: Jon.Sperl@cbo.gov
Subject: CBO TSCA TA Request on cost estimates for House (4-22) compared to S.697

Jon,

This technical assistance responds to the request to compare the estimated costs of the House draft bill (4-22-16) to S.697 (4-28-15).

1. **When Susanne produced the estimate for S. 697 (version ordered reported from EPW on 4/28/2015), she assumed, with feedback from EPA, that that version would require roughly a 30% increase in workload from EPA for its Chemical Risk Review and Reduction program (FY2016 budget is $58 million). Is 30% still a reasonable assumption for this version?**

EPA Response: There are differences in the workload burdens between S. 697 and the draft house bill which create a variety of gives and takes. Some examples include:

- <!--[if !supportLists]--><!--[endif]-->House (4-22) is less prescriptive on policies, guidances and rules
- <!--[if !supportLists]--><!--[endif]-->S. 697 limits manufacturer chemical evaluation requests to not more than 30%; House (4-22) limit is higher at 50%
- <!--[if !supportLists]--><!--[endif]-->House (4-22) removes the Sustainable Chemistry Program

These types of gives and takes will probably result in House (4-22) having a somewhat smaller increase in workload than S. 697.

2. **Fee levels**
   a. **Beginning on pg. 131, the bill describes the allowable levels of fees. There are 3 types of fees in the bill:**

<!--[if !supportLists]--> **i.** <!--[endif]-->**PMN and new fees**

<!--[if !supportLists]--> **ii.** <!--[endif]-->**Additional priority fees (100% defray)**

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b. **I'd like to discuss this section to confirm I have this right, but it seems that the version Susanne analyzed last year would have allowed for up to $18M in PMN/new fees, plus additional priority/work plan fees outside of the cap; she estimated those fees in total would ramp up to $25M/year by 2019.**
c. **This version of the bill appears to increase the cap to $25M/year for PMN/new fees, and then we still have the additional priorities/work plan fees on top of that, so the total amount of fees would be greater, presumably by $7M/year.**
d. **Have I read this correctly? And does EPA have any updated projections of what its fee collections would be under this language?**

EPA Response: The three types of fees are correct, with PMN and new fees covering Sections 4, 5, 6 and 14. With regards to "b" and "c" above, it is unknown how many industry requested risk evaluations EPA would receive, so it is difficult to estimate the fees collected, but $7M seems like a reasonable estimate. Given this, we believe you have summarized the points correctly.

3. **This version does not include language for the Sustainable Chemistry program. It does not appear that Susanne's estimate placed a cost on that program, at least not explicitly. Would the removal of the program from this version reduce EPA's implementation costs at all?**
    a. **Note: Jerry Couri indicates this version of the bill has a "few less new programs." On first glance, it appears to have just one fewer program. I'm not sure what other programs he's referring to.**

EPA Response: The removal of the Sustainable Chemistry Program would reduce EPA's implementation costs (costs to develop and maintain the program). It does not appear the grants funding portion of the program was included in the original estimate but we cannot verify this.

This TA only responds to changes since the last version at the time we were reviewing. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Jon Sperl [mailto:Jon.Sperl@cbo.gov]
Sent: Sunday, April 24, 2016 5:54 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TSCA new languge - quick score

Hi Sven,

I received a request to provide a quick, informal score of the TSCA reform bill, S. 697. I have a few questions that I'm hoping you can help me with before I get back to the committee (hopefully Monday). Here are my questions:

<!--[if !supportLists]-->1. <!--[endif]-->When Susanne produced the estimate for S. 697 (verison ordered reported from EPW on 4/28/2015), she assumed, with feedback from EPA, that that version would require roughly a 30% increase in workload from EPA for its Chemical Risk Review and Reduction program (FY2016 budget is $58 million). Is 30% still a reasonable assumption for this version?

<!--[if !supportLists]-->2. <!--[endif]-->Fee levels

<!--[if !supportLists]-->a. <!--[endif]-->Beginning on pg. 131, the bill describes the allowable levels of fees. There are 3 types of fees in the bill:

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<!--[if !supportLists]-->c. <!--[endif]-->This version of the bill appears to increase the cap to $25M/year for PMN/new fees, and then we still have the additional priorities/work plan fees on top of that, so the total amount of fees would be greater, presumably by $7M/year.

<!--[if !supportLists]-->d. <!--[endif]-->Have I read this correctly? And does EPA have any updated projections of what its fee collections would be under this language?

<!--[if !supportLists]-->3. <!--[endif]-->This version does not include language for the Sustainable Chemistry program. It does not appear that Susanne's estimate placed a cost on that program, at least not explicitly. Would the removal of the program from this version reduce EPA's implementation costs at all?

<!--[if !supportLists]-->a. <!--[endif]-->Note: Jerry Couri indicates this version of the bill has a "few less new programs." On first glance, it appears to have just one fewer program. I'm not sure what other programs he's referring to.

Thanks for fielding my questions. Talk to you soon!

Jon

Jon Sperl

Associate Analyst, Congressional Budget Office

Federal Estimates (EPA), State and Local Gov. Estimates (Energy/Environment/Other)

Ford House Office Building, Room 441-F

(202) 226-9092, jon.sperl@cbo.gov

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Saturday, April 23, 2016 11:40 AM
To: Jon Sperl
Cc: McCarthy, David; Sarley, Chris
Subject: Fw: Your draft.2

Jon:

Attached is legislation our Committee has been working on the Senate to reform title I of the Toxic Substance Control Act (TSCA). This draft is similar to legislation reported by the Senate Committee on Environment and Public Works, with a few less new programs -- like the Green Chemistry grant program. We suspect the score should be close to, but not more than, what you guys had scored that bill last summer. Could you please by email confirm this for us. It is possible the House could consider this bill as early as this week.

Thanks for your time and attention to this. Sorry for the weekend email.

-- jerry

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Brown, Tim D <Tim.Brown@mail.house.gov>

Sent: Friday, April 22, 2016 5:12 PM

To: McCarthy, David; Couri, Jerry; Richards, Tina; Sarley, Chris

Cc: Lin, Kakuti

Subject: Your draft.2

Revised per phone call.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 6/9/2016 5:56:18 PM
To: Jon Sperl [Jon.Sperl@cbo.gov]
Subject: CBO TSCA TA Request on cost estimates for House (4-22) compared to S.697

John,
This responds to the TA request on TSCA cost estimates.

Q: Do you have a projection of fees different from $4M for FY2017?

EPA Response: Based on the timing of the enactment of the bill and the need to put in place a regulation on fees, for FY2017, EPA projects collecting up to $4M in fees.

This TA only responds to House and Senate passed bill. All previously offered TA is still germane to the extent the provision has not changed since the TA was offered. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Jon Sperl [mailto:Jon.Sperl@cbo.gov]
Sent: Wednesday, June 08, 2016 9:40 AM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: RE: CBO TSCA TA Request on cost estimates for House (4-22) compared to S.697

Good morning Sven,

Congrats on the passage of TSCA. For our own scorekeeping, I wanted to run an estimate of fee collections for FY2017 by you. Right now, we are estimating a ramp up with EPA bringing in $4 million in fees in FY2017, going up to $32 million/year by 2021 ($25M for fees under the cap, and another $7M for fees from requested reviews outside the cap).

Do you have a projection of fees different from $4M for FY2017?

Thanks!
Jon

	2017	2018	2019	2020	2021	5 year total
PMN & New Fees (Subject to $25M cap); PMN are exisiting but current cap on them is removed						
BA	0	-6	-12	-18	-25	-61
O	0	-6	-12	-18	-25	-61

Additional Priority Fees 100% defray						
hpl	10	10	10	20	20	
BA	-3	-3	-3	-5	-5	-18
O	-3	-3	-3	-5	-5	-18
Additional Work Plan Fees 50% defray						
	2	2	2	3	3	
BA	-1	-1	-1	-2	-2	-6
O	-1	-1	-1	-2	-2	-6
Total						
BA	-4	-10	-16	-25	-32	-85
O	-4	-10	-16	-25	-32	-85

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Thursday, April 28, 2016 9:52 AM
To: Jon Sperl
Subject: Re: CBO TSCA TA Request on cost estimates for House (4-22) compared to S.697

Jon,
You're welcome. Please let me know if any additional questions. Thanks,
Sven

On Apr 28, 2016, at 9:49 AM, Jon Sperl <Jon.Sperl@cbo.gov> wrote:

Hi Sven,

I just realized I forgot to thank you for your response on this. Thanks very much, especially for the quick turnaround—I know you guys have been slammed!

Have a good rest of the week,
Jon

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, April 25, 2016 7:59 PM
To: Jon Sperl
Subject: CBO TSCA TA Request on cost estimates for House (4-22) compared to S.697

Jon,

This technical assistance responds to the request to compare the estimated costs of the House draft bill (4-22-16) to S.697 (4-28-15).

1. **When Susanne produced the estimate for S. 697 (version ordered reported from EPW on 4/28/2015), she assumed, with feedback from EPA, that that version would require roughly a 30% increase in workload from EPA for its Chemical Risk Review and Reduction program (FY2016 budget is $58 million). Is 30% still a reasonable assumption for this version?**

EPA Response: There are differences in the workload burdens between S. 697 and the draft house bill which create a variety of gives and takes. Some examples include:

- House (4-22) is less prescriptive on policies, guidances and rules
- S. 697 limits manufacturer chemical evaluation requests to not more than 30%; House (4-22) limit is higher at 50%
- House (4-22) removes the Sustainable Chemistry Program

These types of gives and takes will probably result in House (4-22) having a somewhat smaller increase in workload than S. 697.

2. **Fee levels**
   a. **Beginning on pg. 131, the bill describes the allowable levels of fees. There are 3 types of fees in the bill:**
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Please let me know if any questions. Thanks,

Sven

Sven-Erik Kaiser

U.S. EPA

Office of Congressional and Intergovernmental Relations

1200 Pennsylvania Ave., NW (1305A)

Washington, DC 20460

202-566-2753

From: Jon Sperl [mailto:Jon.Sperl@cbo.gov]
Sent: Sunday, April 24, 2016 5:54 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: TSCA new languge - quick score

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Thanks for fielding my questions. Talk to you soon!

Jon

Jon Sperl

Associate Analyst, Congressional Budget Office

Federal Estimates (EPA), State and Local Gov. Estimates (Energy/Environment/Other)

Ford House Office Building, Room 441-F

(202) 226-9092, jon.sperl@cbo.gov

From: Couri, Jerry [mailto:JerryCouri@mail.house.gov]
Sent: Saturday, April 23, 2016 11:40 AM
To: Jon Sperl
Cc: McCarthy, David; Sarley, Chris
Subject: Fw: Your draft.2

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Attached is legislation our Committee has been working on the Senate to reform title I of the Toxic Substance Control Act (TSCA). This draft is similar to legislation reported by the Senate Committee on Environment and Public Works, with a few less new programs -- like the Green Chemistry grant program. We suspect the score should be close to, but not more than, what you guys had scored that bill last summer. Could you please by email confirm this for us. It is possible the House could consider this bill as early as this week.

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Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

From: Brown, Tim D <Tim.Brown@mail.house.gov>

Sent: Friday, April 22, 2016 5:12 PM

To: McCarthy, David; Couri, Jerry; Richards, Tina; Sarley, Chris

Cc: Lin, Kakuti

Subject: Your draft.2

Revised per phone call.

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/24/2015 10:38:48 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]; 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: TSCA Reform TA - Fee Scenarios

Dimitri,
The approach we used is similar to how we calculate the percentage of the pesticides program paid by fees. We're not just adding 20%, 25%, or 30% to the base program, we are looking at the overall program and making the calculation from that. The denominator includes the appropriated dollars plus fees. The numerator is the fees. The result is then the percentage of the total resources paid by fees. One way to look at is to determine what you want the percentage to be and calculate the fees. Another way would be to assume how much people would be willing to pay and calculate from that. The size of the program and the number of chemicals assessed follow from that.

Here's the math to find how much it would cost for different fee levels where:
- Base + fees = new program total
- fees = a set percent of the new program total

Assume:
1. Base = $56M
2. x = fees generated
3. y = new total
4. z = 20% fee

Then:
1. 56 + x =y
2. x = y*z
3. x = y* 0.20= y/5
4. 56 + (y/5) = y
5. 56 = y- (y/5)
6. 56 = 4/5y
7. y = (56 * 5)/4
8. y = 280/4
9. y = $70M [program total at 20%]
10. x = 70-56 = $14M [fees generated at 20%]

You can substitute a different percentage (z) and get a new program total (y) and fees generated (x)

Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Monday, February 23, 2015 5:15 PM

To: Kaiser, Sven-Erik; Black, Jonathan (Tom Udall)
Subject: RE: TSCA Reform TA - Fee Scenarios

In further looking at this it seems like you all went about the calculations in a strange way. You cannot add the estimated fees to the current "base" then calculate the percentage. 20% of current $56 million would be $11.2 million. In order to get $14 million in fees you would have to have 25% fees from the baseline number.

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Monday, February 23, 2015 4:41 PM
To: Karakitsos, Dimitri (EPW); Black, Jonathan (Tom Udall)
Subject: RE: TSCA Reform TA - Fee Scenarios

Dimitri and Jonathan,

We started with $56M as our current "base" for new and existing chemicals work. We then added fee amounts. The percentage was then calculated using the fees as a percentage of the new totals. We caveat that although there has been discussion of fees for new chemical submissions, those fees are not included here as either additional amounts or in the calculation of percentages.

At 20%, we estimate would raise $14M in fees, bringing the program total to $70M.

At 25%, we estimate would raise $19M in fees, bringing the program total to $75M.

At 30%, I calculated that we would raise $24M in fees, bringing the program total to $80M.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Friday, February 20, 2015 1:21 PM
To: Kaiser, Sven-Erik; Black, Jonathan (Tom Udall)
Subject: RE: TSCA Reform TA - Fee Scenarios

Sven – quick follow up here. Can you give me an idea of what EPA expects to raise at each fee percentage? We had a somewhat confusing discussion about each percentage being a percentage of what (if that makes sense). If we could know what numbers EPA calculated it would raise at 20%, 25%, and 30%, it would let us know the total pot you all were working from.

Please let me know if that makes sense or if you want to follow up and thanks for your help with this.

Dimitri

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, February 18, 2015 12:07 PM
To: Karakitsos, Dimitri (EPW); Black, Jonathan (Tom Udall)
Subject: TSCA Reform TA - Fee Scenarios

Jonathan and Dimitri,

In response to your request, please see attached technical assistance on fee scenarios. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/23/2015 9:41:25 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]; 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: RE: TSCA Reform TA - Fee Scenarios

Dimitri and Jonathan,

We started with $56M as our current "base" for new and existing chemicals work. We then added fee amounts. The percentage was then calculated using the fees as a percentage of the new totals. We caveat that although there has been discussion of fees for new chemical submissions, those fees are not included here as either additional amounts or in the calculation of percentages.

At 20%, we estimate would raise $14M in fees, bringing the program total to $70M.

At 25%, we estimate would raise $19M in fees, bringing the program total to $75M.

At 30%, I calculated that we would raise $24M in fees, bringing the program total to $80M.

Please let me know if any additional questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Karakitsos, Dimitri (EPW) [mailto:Dimitri_Karakitsos@epw.senate.gov]
Sent: Friday, February 20, 2015 1:21 PM
To: Kaiser, Sven-Erik; Black, Jonathan (Tom Udall)
Subject: RE: TSCA Reform TA - Fee Scenarios

Sven – quick follow up here. Can you give me an idea of what EPA expects to raise at each fee percentage? We had a somewhat confusing discussion about each percentage being a percentage of what (if that makes sense). If we could know what numbers EPA calculated it would raise at 20%, 25%, and 30%, it would let us know the total pot you all were working from.

Please let me know if that makes sense or if you want to follow up and thanks for your help with this.

Dimitri

From: Kaiser, Sven-Erik [mailto:Kaiser.Sven-Erik@epa.gov]
Sent: Wednesday, February 18, 2015 12:07 PM
To: Karakitsos, Dimitri (EPW); Black, Jonathan (Tom Udall)
Subject: TSCA Reform TA - Fee Scenarios

Jonathan and Dimitri,
In response to your request, please see attached technical assistance on fee scenarios. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 7/10/2015 9:56:03 PM
To: 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]; 'Freedhoff, Michal (Markey)' [Michal_Freedhoff@markey.senate.gov]; 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]; 'Hunt, Jasmine (Durbin)' [Jasmine_Hunt@durbin.senate.gov]; 'Zimmerman, Melissa (Appropriations)' [Melissa_Zimmerman@appro.senate.gov]
Subject: Senate TSCA TA on Appropriations and Fees
Attachments: Senate TSCA TA on Fees and Appropriations.docx

Jonathan,
The attached technical assistance responds to your request. The technical assistance is intended for use only by the requester. The technical assistance does not necessarily represent the policy positions of the agency and the administration on the bill, the draft language and the comments. Please let me know if any questions.
Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Black, Jonathan (Tom Udall) [mailto:Jonathan_Black@tomudall.senate.gov]
Sent: Friday, July 10, 2015 2:09 PM
To: Kaiser, Sven-Erik
Cc: Freedhoff, Michal (Markey); Karakitsos, Dimitri (EPW); Hunt, Jasmine (Durbin); Zimmerman, Melissa (Appropriations)
Subject: Minimum appropriations

Sven, can you run this construct by your folks to ensure that this is appropriately drafted? Based on our conversations with you yesterday.

> "(D) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2014) of the ~~Office of Pollution Prevention and Toxics of the Environmental Protection Agency for~~ Chemical Risk Review and Reduction activity of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for covered functions for fiscal year 2014 (excluding the amount of any fees appropriated for the fiscal year).

Message

From: Kaiser, Sven-Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AC78D3704BA94EDBBD0DA970921271FF-SKAISER]
Sent: 2/18/2015 5:07:11 PM
To: 'Karakitsos, Dimitri (EPW)' [Dimitri_Karakitsos@epw.senate.gov]; 'Black, Jonathan (Tom Udall)' [Jonathan_Black@tomudall.senate.gov]
Subject: TSCA Reform TA - Fee Scenarios
Attachments: TSCA Reform TA.Fee Scenarios.docx

Jonathan and Dimitri,
In response to your request, please see attached technical assistance on fee scenarios. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

Message

From: Sadowsky, Don [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1209038134DA47C6AA6D6AB720347D1B-SADOWSKY, DON]
Sent: 4/14/2016 3:49:14 PM
To: Grant, Brian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec6104b72cab42ba9b1e1da67d4288ae-Grant, Brian]; Mclean, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=869a9152d655420594d8f94a966b8892-KMCLEAN]; Berol, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a227f36ca9ee4eeb98a95cb22058de43-DBerol]
Subject: RE: Sen. Markey TSCA TA Request on Section 14 (4-12)
Attachments: ~$-MFARP16096_XML BG-ds.doc

Just a couple minor comments on your comments.

Donald A. Sadowsky
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W. 20460
(202) 564-5638

From: Grant, Brian
Sent: Thursday, April 14, 2016 11:40 AM
To: Sadowsky, Don <Sadowsky.Don@epa.gov>; Mclean, Kevin <Mclean.Kevin@epa.gov>; Berol, David <Berol.David@epa.gov>
Subject: Re: Sen. Markey TSCA TA Request on Section 14 (4-12)

Brian Grant
Office of General Counsel
202-564-5503

From: Sadowsky, Don
Sent: Wednesday, April 13, 2016 9:13 AM
To: Mclean, Kevin; Grant, Brian; Berol, David
Subject: RE: Sen. Markey TSCA TA Request on Section 14 (4-12)

I've looked at the revised bill language. I have only two comments:

1. Re-health and safety studies: wow! They've reverted mostly back to the original language in TSCA. I don't know whether what we saw earlier was a trial balloon, or whether they were looking for the Agency to indicate that the limitations on disclosure of chemical identity are problematic, but for whatever reason, the limitations have disappeared. I do not have any specific comments on the reformulated language.
2. At the end of (d)(1)(G) Michal thinks that "and" should be replaced with "or". She is correct, and that is consistent with current TSCA 14(a).

Donald A. Sadowsky
Pesticides and Toxic Substances Law Office
Office of General Counsel

U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W. 20460
(202) 564-5638

From: Kaiser, Sven-Erik
Sent: Tuesday, April 12, 2016 6:31 PM
To: Sadowsky, Don <Sadowsky.Don@epa.gov>; Berol, David <Berol.David@epa.gov>; Brown, Tristan <Brown.Tristan@epa.gov>; Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>; Distefano, Nichole <DiStefano.Nichole@epa.gov>; Flattery, Priscilla <Flattery.Priscilla@epa.gov>; Grant, Brian <Grant.Brian@epa.gov>; Jones, Jim <Jones.Jim@epa.gov>; Mclean, Kevin <Mclean.Kevin@epa.gov>; Schmit, Ryan <schmit.ryan@epa.gov>
Subject: Sen. Markey TSCA TA Request on Section 14 (4-12)

TSCA Team – Please see Michal's TA request on the Senate leg counsel version with her RLSO edits. Tomorrow (Weds, Apr 13) ok. Please let me know if any questions. Thanks,
Sven

Sven-Erik Kaiser
U.S. EPA
Office of Congressional and Intergovernmental Relations
1200 Pennsylvania Ave., NW (1305A)
Washington, DC 20460
202-566-2753

From: Freedhoff, Michal (Markey) [mailto:Michal_Freedhoff@markey.senate.gov]
Sent: Tuesday, April 12, 2016 5:49 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject: Section 14

PLs review

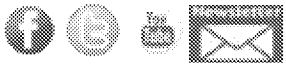
Message

From: Freedhoff, Michal (Markey) [Michal_Freedhoff@markey.senate.gov]
Sent: 5/21/2016 1:39:13 AM
To: Jones, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c32c4b9347004778b0a93a4cbd83fc8a-JJONES1]
CC: Distefano, Nichole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31d32a3a3a9e4591b5fdfc3eb96e8b78-Distefano,]; Schmit, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7077ecbac4914a00ad465398f92bbe78-Schmit, Ryan]
Subject: RE: section 21 drafting

I assume you are sending this back in your set (along w other similar issues)? I am putting some of these into our document as well.

Michal Ilana Freedhoff, Ph.D.
Director of Oversight & Investigations
Office of Senator Edward J. Markey
255 Dirksen Senate Office Building
Washington, DC 20510
202-224-2742

Connect with Senator Markey



From: Jones, Jim [mailto:Jones.Jim@epa.gov]
Sent: Thursday, May 19, 2016 9:24 PM
To: Freedhoff, Michal (Markey)
Cc: Distefano, Nichole; Schmit, Ryan
Subject: section 21 drafting

Michal, let us know if this works (or not). Jim

> On p 174 of the HLC 5/19 3:23 pm draft, strike lines 11-14 and replace it with:
>
> (iii) in clause (ii), by striking "section 6 or 8" and all that follows through the end of the clause and inserting "section 6(a) or 8 or an order under section 5(f), the chemical substance or mixture to be subject to such rule or order presents or will present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use"

Message

From: Schmit, Ryan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7077ECBAC4914A00AD465398F92BBE78-SCHMIT, RYAN]
Sent: 4/15/2016 9:05:31 PM
To: Michal_Freedhoff@markey.senate.gov
Subject: draft pbt options
Attachments: PBT Options, 4.15.16.docx

Brian's Option

( ) Chemicals That Are Persistent, Bioaccumulative, and Toxic.--

(1) Expedited Action.--Not later than 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall propose rules under subsection (a) with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments —

(A) that the Administrator has a reasonable basis to conclude are toxic and with respect to persistence and bioaccumulation, scores high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation, initiated a review under section 5, or entered into a consent agreement under section 4 prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; and

(B) exposure to which under the conditions of use is likely to the general population, a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator.

(2) Except as provided in paragraph (5), the Administrator shall not be required to conduct risk evaluations under section 6(b) on chemical substances that are subject to paragraph (1).

(3) Final Rule.--Notwithstanding subsections (__),subject to subsections __ and __ , not later than 18 months after proposing a rule pursuant to paragraph (1), the Administrator shall promulgate a rule under subsection (a).

(4) In selecting among prohibitions and other restrictions promulgated in a rule under subsection (a) pursuant to paragraph (1), the Administrator shall address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance ~~ensure that the chemical substance subject to the rule does not present any unreasonable risk of injury to health or the environment identified by the Administrator, without consideration of costs or other non-risk factors, including an unreasonable risk of injury to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator,~~ and shall reduce exposure to the substance to the extent practicable.

(5) Relationship to subsection (b).--If, at any time prior to the date that is 90 days after the date on which the Administrator proposes a rule under paragraph (1) with respect to a chemical substance, the Administrator makes a finding under subsection (__), or a manufacturer requests a risk evaluation under subsection (__), with respect to the chemical substance, such chemical substance shall not be subject to this subsection, except that in selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a), the Administrator shall both ensure that the chemical substance meets the rulemaking standard under subsection (a) and reduce exposure to the substance to the extent practicable.

(5) OTHER CHEMICALS THAT ARE PERSISTENT, BIOACCUMULATIVE, AND TOXIC OR CARCINOGENS.—

(A) In designating high priority substances pursuant to subsection (b), the Administrator shall give preference to—

(i) chemical substances that, with respect to persistence and bioaccumulation, score high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system) ;and

(ii) chemical substances listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity.

(B) In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007 (or a successor document), and may use other applicable information consistent with the best available science.

(C) For a chemical substance subject to subsection (a) that with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system) the Administrator shall, in selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a), both ensure that the chemical substance meets the rulemaking standard under subsection (a) and reduce exposure to the substance to the extent practicable.
Retain expedited action provision in 6(c)

(C) may extend the deadlines under this paragraph for not more than two years, subject to the condition that the aggregate length of extensions under this paragraph and subsection (b)(4)(G) does not exceed two years, and subject to the limitation that the Administrator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

Ryan's Option

[Brian's Option], plus edits to 6(a) in blue:

(a) SCOPE OF REGULATION.—If the Administrator ~~finds that there is a reasonable basis to conclude that~~ determines in accordance with subsection (b)(4)(A) the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents, or will present an unreasonable risk of injury to health or the environment, or ~~designates a chemical subsection under subsection~~ otherwise identifies a risk pursuant to [XX/section 6 pbts], the Administrator shall by rule and subject to section 18, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary to ~~protect adequately against such risk using the least burdensome requirements~~ so that the chemical substance no longer presents such risk:

Michal's Option

(a) SCOPE OF REGULATION. If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, [or, for a chemical substance designated under subsection PBT, the risk posed by the substance as evaluated under subsection (exposure assessment)], the Administrator shall by rule, and subject to section 18 and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance no longer presents such risk.:

[Clarification from Michal that the bracketed "exposure assessment" means the determination under (X)(1)(B) that "exposure . . . under the conditions of use is likely to the general population, a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator"

Message

From: Schmit, Ryan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7077ECBAC4914A00AD465398F92BBE78-SCHMIT, RYAN]
Sent: 5/20/2016 7:58:41 PM
To: Jason_Albritton@epw.senate.gov; Bettina_Poirier@epw.senate.gov
Subject: FW:
Attachments: section 18 fix.docx

From: Schmit, Ryan
Sent: Friday, May 20, 2016 3:57 PM
To: Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>
Subject:

Ryan N. Schmit
Special Assistant to Jim Jones, Assistant Administrator
Office of Chemical Safety and Pollution Prevention (OCSPP)
Telephone: 202-564-0610
Email: schmit.ryan@epa.gov

Message

From: Vaught, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C30920BCB6214A91B7E3C1E7810C63E1-VAUGHT, LAURA]
Sent: 9/25/2015 8:40:44 PM
To: Poirier, Bettina (EPW) [Bettina_Poirier@epw.senate.gov]
CC: Jason (EPW) Albritton (Jason_Albritton@epw.senate.gov) [Jason_Albritton@epw.senate.gov]
Subject: FW: TA on "Option 3"
Attachments: Option 3 -- TA.docx

Bettina - apologies that I forgot to copy you.

From: Vaught, Laura
Sent: Friday, September 25, 2015 4:24 PM
To: Jason (EPW) Albritton (Jason_Albritton@epw.senate.gov)
Subject: FW: TA on "Option 3"

Jason - per earlier discussion, attached is technical assistance.

This does 2 things:

- Adds notice requirement for states issuing requirements during the window between designation as a high priority and EPA completion of safety determination.
- Cleans up the criteria for the extension of 3.5 years to 4 years (EPA hasn't yet received data required to be developed for the high priority substance)

OPTION 3

"SEC. 4A. PRIORITIZATION SCREENING.

...

"(b) Prioritization Screening Process and Decisions.—

...

"(9) OTHER INFORMATION RELEVANT TO PRIORITIZATION.—

"(A) IN GENERAL.—If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State proposes an administrative action or enacts a statute or takes an administrative action to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not designated as a high-priority substance, the Governor or State agency with responsibility for implementing the statute or administrative action shall notify the Administrator.

"(B) REQUESTS FOR INFORMATION.—Following receipt of a notification provided under subparagraph (A), the Administrator may request any available information from the Governor or the State agency with respect to—

"(i) scientific evidence related to the hazards, exposures and risks of the chemical substance under the conditions of use which the statute or administrative action is intended to address;

"(ii) any State or local conditions which warranted the statute or administrative action;

"(iii) the statutory or administrative authority on which the action is based; and

"(iv) any other available information relevant to the prohibition or other restriction, including information on any alternatives considered and their hazards, exposures, and risks.

"(C) PRIORITIZATION SCREENING.—The Administrator shall conduct a prioritization screening under this subsection for all substances that—

"(i) are the subject of notifications received under subparagraph (A); and

"(ii) the Administrator determines—

"(I) are likely to have significant health or environmental impacts;

"(II) are likely to have significant impact on interstate commerce; or

"(III) have been subject to a prohibition or other restriction under a statute or administrative action in 2 or more States.

"(D) POST-PRIORITIZATION NOTICE.—If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State proposes an administrative action or enacts a statute or takes an administrative action to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a high-priority substance, after the date on which the deadline established pursuant to section 6(a) for completion of the safety determination under section 6(a) expires but

Commented [A1]: From 9(A), except flip the "has not designated" to "has designated"

Commented [A2]: Copied from 18(b)(1).

OPTION 3

before the date on which the Administrator publishes the safety determination under section 6(a), the Governor or State agency with responsibility for implementing the statute or administrative action shall notify the Administrator.

"(~~I~~J) AVAILABILITY TO PUBLIC.—Subject to section 14 and any applicable State law regarding the protection of confidential information provided to the State or to the Administrator, the Administrator shall make information received from a Governor or State agency under subparagraph (A) or (I) publicly available.

"(~~J~~K) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall preempt a State statute or administrative action, require approval of a State statute or administrative action, or apply section 15 to a State.

Commented [A3]: Presume drafters do not intend for this notice obligation to extend beyond the date that the safety determination is published, since under prior drafting there would have been no need for the state to apply for a waiver during the period between the issuance of a negative safety determination and the effective date of a risk management rule under 6(d).

Commented [A4]: Presume drafters would intend both of these provisions to apply to 4(b)(9)(D) notices, just like 4(b)(9)(A) notices.

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections ~~(g)~~**(h)** and ~~(h)~~**(i)**, respectively;

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) shall, as soon as practicable and not later than 6 months after the date on which a chemical substance is designated as a high-priority substance, define and publish the scope of the safety assessment and safety determination to be conducted pursuant to this section, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that the Administrator expects to consider;

"(3) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(4) shall complete **and publish** a safety assessment and safety determination not later than 3 years and 6 months after the date on which a chemical substance is designated as a high-priority substance;

"(5) shall promulgate ~~a~~ **any necessary** final rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed;

"(6) may extend the deadline under paragraph (4) for no more than 180 days, if ~~a test~~information relating to the high priority substance, required to be developed in a rule, order or consent agreement ~~promulgated or issued~~ under Section 4, ~~is in effect~~has not yet been submitted to the Administrator; and

"(7) may extend the deadline under paragraph (5) for no more than 2 years, subject to the

Commented [A5]: This language is derives from 4(a)(1): "The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section"

Also clarifies that the unmet information requirement must be about the same high priority substance for which the deadline is being extended.

Commented [A6]: These words are unnecessary, and incomplete, since consent agreements are "entered into," per 4(a)(3).

It would also be clear, but wordier, to say "promulgated, issued, or entered into under Section 4"

Commented [A7]: Narrowed per drafting directions. Note that rules, orders, and consent agreements have legal consequences that extend beyond the date that the information is submitted, and thus could be said to still be "in effect." See 4(d)(2)(B)(iii)(I).

OPTION 3

condition that the aggregate length of all extensions of deadlines under this subsection does not exceed 2 years.

SEC. 17. STATE-FEDERAL RELATIONSHIP.

"(b) New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions.—

"(1) IN GENERAL.—Except as provided in subsections (c), (d), ~~and~~(e), **(f), and (g),** beginning on the date on which the Administrator defines **and publishes** the scope of a safety assessment and safety determination under section 6(a)(2) and ending on the date on which the deadline established pursuant to section 6(a) for completion of the safety determination expires, or on the date on which the Administrator publishes the safety determination **under section 6(a)**, whichever is earlier, no State or political subdivision of a State may establish a statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance designated under section 4A.

Message

From: Albritton, Jason (EPW) [Jason_Albritton@epw.senate.gov]
Sent: 10/2/2015 4:37:30 PM
To: Vaught, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c30920bcb6214a91b7e3c1e7810c63e1-Vaught, Laura]
Subject: Cancer Clusters and Ozone
Attachments: TAM15873_XML.DOC

Can we get EPA's quick technical assistance on the attached cancer cluster provision? It is being considered for the TSCA bill. So, we need feedback this afternoon.

Also, Bettina would like to speak with EPA's experts on the ozone standard at 2:30. Sen. Boxer has some questions about the standard and the health impacts that she would like clarified. Can you let me know if that would work?

Thanks.

Jason Albritton
Senior Policy Advisor
Senate Committee on Environment and Public Works
Senator Barbara Boxer, Ranking Member
456 Dirksen Senate Office Building

Tel: 202-224-8832
Fax: 202-224-1273

Title: To provide the appropriate Federal agencies with the authority and resources to investigate potential cancer clusters.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Trevor Schaefer Cancer Cluster Identification and Response Act".

SEC. 2. PURPOSE.

The purposes of this Act are—

(1) to provide the appropriate Federal agencies with the authority to help conduct investigations into potential cancer clusters;

(2) to ensure that Federal agencies have the authority to undertake actions to help address cancer clusters and factors that may contribute to the creation of potential cancer clusters; and

(3) to enable Federal agencies to coordinate with other Federal, State, and local agencies, institutes of higher education, and the public in investigating and addressing cancer clusters.

SEC. 3. DESIGNATION AND INVESTIGATION OF POTENTIAL CANCER CLUSTERS.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399V–6. DESIGNATION AND INVESTIGATION OF POTENTIAL CANCER CLUSTERS.

"(a) Definitions.—In this section:

"(1) CANCER CLUSTER.—The term 'cancer cluster' means the incidence of a particular cancer within a population group, a geographical area, or a period of time that is greater than expected for such group, area, or period.

"(2) PARTICULAR CANCER.—The term 'particular cancer' means one specific type of cancer or a type of cancers scientifically proven to have the same cause.

"(3) POPULATION GROUP.—The term 'population group' means a group, for purposes of calculating cancer rates, defined by factors such as race, ethnicity, age, or gender.

"(b) Criteria for Designation of Potential Cancer Clusters.—

"(1) DEVELOPMENT OF CRITERIA.—The Secretary shall develop criteria for the designation of potential cancer clusters.

"(2) REQUIREMENTS.—The criteria developed under paragraph (1) shall, at a minimum—

"(A) include a standard for cancer cluster identification and reporting protocols used to determine when cancer incidence is greater than would be typically observed;

"(B) include scientific screening standards that ensure that a cluster of a particular cancer involves the same type of cancer, or types of cancers;

"(C) define the population in which the cluster of a particular cancer occurs by factors such as race, ethnicity, age, and gender, for purposes of calculating cancer rates;

"(D) define the boundaries of a geographic area in which a cluster of a particular cancer occurs so as not to create or obscure a potential cluster by selection of a specific area; and

"(E) define the time period over which the number of cases of a particular cancer, or the calculation of an expected number of cases, occurs.

"(c) Guidelines for Investigation of Potential Cancer Clusters.—The Secretary, in consultation with the Council of State and Territorial Epidemiologists and representatives of State and local health departments, shall develop, publish, and periodically update guidelines for investigating potential cancer clusters. The guidelines shall—

"(1) require that investigations of cancer clusters—

"(A) use the criteria developed under subsection (b);

"(B) use the best available science; and

"(C) rely on a weight of the scientific evidence;

"(2) provide standardized methods of reviewing and categorizing data, including from health surveillance systems and reports of potential cancer clusters; and

"(3) provide guidance for using appropriate epidemiological and other approaches for investigations.

"(d) Investigation of Cancer Clusters.—

"(1) SECRETARY DISCRETION.—The Secretary shall have the discretion to prioritize certain potential cancer clusters in conducting investigations, based on the availability of resources.

"(2) COORDINATION.—In investigating potential cancer clusters, the Secretary shall coordinate with agencies within the Department of Health and Human Services, such as the Agency for Toxic Substances and Disease Registry, and other Federal agencies, such as the Environmental Protection Agency.

"(3) BIOMONITORING.—In investigating potential cancer clusters, the Secretary shall rely on all appropriate biomonitoring information collected under other Federal programs, such as the National Health and Nutrition Examination Survey. The Secretary may provide technical assistance for relevant biomonitoring studies of other Federal agencies.

"(e) Duties.—The Secretary shall—

"(1) ensure that regional staff of such agencies are prepared to provide timely assistance, to the extent practicable, upon receiving a request to investigate a potential cancer cluster

from a State or local health authority;

"(2) maintain staff expertise in epidemiology, toxicology, data analysis, environmental health and cancer surveillance, exposure assessment, pediatric health, pollution control, community outreach, health education, laboratory sampling and analysis, spatial mapping, and informatics;

"(3) consult with community members as investigations into potential cancer clusters are conducted, as the Secretary determines appropriate;

"(4) collect, store, and disseminate reports on investigations of potential cancer clusters, the possible causes of such clusters, and the actions taken to address such clusters; and

"(5) provide technical assistance for investigating cancer clusters to State and local health departments through existing programs, such as the Epi-Aids program of the Centers for Disease Control and Prevention and the Assessments of Chemical Exposures program of the Agency for Toxic Substances and Disease Registry.".

Message

From: Albritton, Jason (EPW) [Jason_Albritton@epw.senate.gov]
Sent: 9/25/2015 5:27:26 PM
To: Vaught, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c30920bcb6214a91b7e3c1e7810c63e1-Vaught, Laura]
CC: Poirier, Bettina (EPW) [Bettina_Poirier@epw.senate.gov]
Subject: Option 3.docx
Attachments: Option 3.docx

For the 2 pm call.

OPTION 3

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections ~~(g)~~**(h)** and ~~(h)~~**(i)**, respectively;

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) shall, as soon as practicable and not later than 6 months after the date on which a chemical substance is designated as a high-priority substance, define and publish the scope of the safety assessment and safety determination to be conducted pursuant to this section, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that the Administrator expects to consider;

"(3) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(4) shall complete **and publish** a safety assessment and safety determination not later than 3 years and 6 months after the date on which a chemical substance is designated as a high-priority substance;

"(5) shall promulgate ~~a~~ **any necessary** final rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed;

"(6) may extend the deadline under paragraph (4) for no more than 180 days, if a test rule, order or consent agreement promulgated or issued under Section 4 is in effect; and

"(7) may extend the deadline under paragraph (5) for no more than 2 years, subject to the condition that the aggregate length of all extensions of deadlines under this subsection does not exceed 2 years.

SEC. 17. STATE-FEDERAL RELATIONSHIP.

"(b) New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions.—

"(1) IN GENERAL.—Except as provided in subsections (c), (d), ~~and~~(e), **(f), and (g),** beginning on the date on which the Administrator defines **and publishes** the scope of a safety assessment and safety determination under section 6(a)(2) and ending on the date on which the deadline established pursuant to section 6(a) for completion of the safety determination expires, or on the date on which the Administrator publishes the safety determination **under section 6(a)**, whichever is earlier, no State or political subdivision of a State may establish a statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance designated under section 4A.

Message

From: Poirier, Bettina (EPW) [Bettina_Poirier@epw.senate.gov]
Sent: 4/30/2015 9:28:08 AM
To: Vaught, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c30920bcb6214a91b7e3c1e7810c63e1-Vaught, Laura]
Subject: Fwd: EPA Adm McCarthy comments on asbestos/TSCA

Please make sure gina sees the afl, adao and heinzerling analysis below. NRDC safer and the groups are working to strengthen the standard too. Litigation problem needs to be fixed. Vitter opposes asbestos regulation/ban - it is used heavily in his state. It is not an accident that he won't fix it.

Sent from my iPad

Begin forwarded message:

> **From:** "Gilman, Kate (EPW)" <Kate_Gilman@epw.senate.gov>
> **Date:** April 29, 2015 at 5:46:32 PM EDT
> **To:** Sam Pearson <spearson@eenews.net>
> **Cc:** "Poirier, Bettina (EPW)" <Bettina_Poirier@epw.senate.gov>
> **Subject: RE: EPA Adm McCarthy comments on asbestos/TSCA**
>
> Hi Sam,
>
> We also wanted to send you AFL-CIO and the Asbestos Disease Awareness Organization (ADAO) statements on the amended toxic chemical bill that was voted on yesterday in committee:
> AFL-CIO:
> http://www.epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=d7058314-7cd8-4638-8c11-9c5b8387cc5d
> ADAO:
> http://www.epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=a3a7019d-4489-4404-84e8-49fe5f3b6a9c
>
> On background, here is a blog post from Lisa Heinzerling, Justice William J. Brennan, Jr., Professor of Law, Georgetown University Law Center, titled: "Toxic Ambiguity: The Dangerous Mixed Messages of the Udall-Vitter Bill to Reform TSCA":
> http://www.acslaw.org/acsblog/toxic-ambiguity-the-dangerous-mixed-messages-of-the-udall-vitter-bill-to-reform-tsca
>
> Hope this helps.
>
> Best,
>
> Kate

From: Poirier, Bettina (EPW)
Sent: Wednesday, April 29, 2015 5:38 PM

To: Sam Pearson
Cc: Gilman, Kate (EPW)
Subject: Re: EPA Adm McCarthy comments on asbestos/TSCA

Otr Gina does not say it would be regulated. Listing as a priority is not even close to establishing a safeguard that withstands legal challenge. In fact, Epa treated asbestos as one of its highest priorities before the corrosion proof fittings case but could not regulate after the court reviewed the standards. Even naming asbestos a priority, which there is no assurance any future epa would do-- depending on the administration--is just starting the process. That's all she is saying. She is not saying the hurdles are gone and she is not saying Udall is right it will be regulated and withstand legal challenge. There is in fact a serious set of legal problems. Boxer relies upon legal scholars for this concern like lisa heinzerling, professor at Georgetown law and recent epa official in the obama administration. To address this, we have suggested language, including specific language on asbestos because it is so well known as a lethal material. We will forward lisa heinzerlings recent analysis. Serious problems and obstacles to regulation remain in substitute. Wish it were not the case. The asbestos group leaders have met with udal but we understood he couldn't get his legislative partners to make the needed changes, not even the most basic. Linda Reinstein is key voice on this and afl cio.

Sent from my iPad

On Apr 29, 2015, at 5:10 PM, Sam Pearson <spearson@eenews.net> wrote:

> This was the relevant section:
> Senator Udall: Administrator McCarthy, I know you're aware that the senate environment and public works committee reported TSCA reform legislation yesterday on a strong bipartisan basis. I introduced that bill with Senator Vitter and a broad array of bipartisan cosponsors. Our goal is to finally make some headway and give epa the ability to set protective standards based on science to protect all Americans from toxic chemicals especially the most vulnerable populations like pregnant women and young children. The american people would be shocked to know that epa has not regulated a toxic chemical under the primary law in over 20 years. At a hearing on the bill your assistant administrator jim jones testified that met all this administration's principles for reform, and yesterday's markup involved even further key improvements. Can you confirm that the bill as amended meets the EPA's goals for TSCA reform, and are you encouraged by the bipartisan momentum on this bill?
>
> McCarthy: Well I am aware that Mr. Jones identified a couple of areas where the bill fell short of the administration's principles but I also am pleased that the most recent ams really addressed those issues, and I am encouraged that we're moving forward with a bipartisan bill.
>
> Udall: The poster child for TSCA reform is asbestos. The fifth circuit threw out EPA's asbestos rule in 1991 in a case called Corrosion Proof Fittings citing the difficult standards in the law, which led us to the situation today of no real federal chemical regulation. Would the bill reported yesterday by the EPW committee give EPA the tools it needs to act on asbestos and if a law is enacted would EPA consider asbestos a strong candidate for early action?
>
> Mccarthy: Well EPA would have the authority to make asbestos what we call now a high priority chemical, and with that the agency would be on a schedule for assessing and making regulatory determinations for asbestos.

From: Sam Pearson
Sent: Wednesday, April 29, 2015 5:03 PM
To: Gilman, Kate (EPW); Kerr, Mary (EPW); 'Poirier, Bettina (EPW)'
Subject: EPA Adm McCarthy comments on asbestos/TSCA

Hi, I saw that Administrator McCarthy said today at the Senate Appropriations Committee, in response to a question from Senator Tom Udall, that she thought EPA would be able to regulate asbestos under his bill. Since Senator Boxer has said that she believes that regulation of asbestos would never happen under this law, did you want to comment at all on Administrator McCarthy's statement? Is Administrator McCarthy mistaken that EPA would have this authority?

Thanks,

Sam Pearson
Reporter, *Greenwire*
spearson@eenews.net
202-446-0452 (desk)
202-422-5100 (cell)

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Message

From: Poirier, Bettina (EPW) [Bettina_Poirier@epw.senate.gov]
Sent: 4/22/2015 8:10:28 PM
To: Vaught, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c30920bcb6214a91b7e3c1e7810c63e1-Vaught, Laura]
Subject: FW: what is the latest on the chairmans mark
Attachments: WEI15432.pdf; redline.doc

Purpose: In the nature of a substitute.

S. 697

To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE INTENDED TO BE PROPOSED BY _____

Viz:

Strike all after the enacting clause and insert the following:

~~Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act".

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(c) of the Toxic Substances Control Act (15 U.S.C. 2601(c)) is amended—

(1) by striking "It is the intent" and inserting the following:

"(1) ADMINISTRATION.—It is the intent";

(2) in paragraph (1) (as so redesignated), by inserting ", as provided under this Act" before the period at the end; and

(3) by adding at the following:

"(2) REFORM.—It is the intent of Congress that reform of this Act in accordance with the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act—

"(A) shall be administered in a manner that—

"(i) protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and

"(ii) ensures that appropriate information on chemical substances and mixtures is available to public health officials and first responders in the event of an emergency; and

"(B) shall not displace or supplant common law rights of action or remedies for civil relief.".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) by redesignating paragraphs (4), (5), (6), (7), (8), (9), (10), (11), (12), (13), and (14) as paragraphs (5), (6), (7), (8), (9), (10), (12), (13), (17), (18), and (19), respectively;

(2) by inserting after paragraph (3) the following:

"(4) CONDITIONS OF USE.—The term 'conditions of use' means the intended, known, or reasonably foreseeable circumstances the Administrator determines a chemical substance is manufactured, processed, distributed in commerce, used, or disposed of.";

(3) by inserting after paragraph (10) (as so redesignated) the following:

"(11) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.—The term 'potentially exposed or susceptible population' means 1 or more groups—

"(A) of individuals within the general population who may be—

"(i) differentially exposed to chemical substances under the conditions of use; or

"(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

"(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; and

(4) by inserting after paragraph (13) (as so redesignated) the following:

"(14) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.

"(15) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the conditions of use.

"(16) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of harm to health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of harm to—

"(A) the general population; or

"(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

The Toxic Substances Control Act is amended by inserting after section 3 (15 U.S.C. 2602) the following:

"SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

"(a) Definition of Guidance.—In this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.

"(b) Deadline.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.

"(c) Use of Science.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance on the use of science in making decisions under sections 4, 4A, 5, and 6.

"(2) GOAL.—A goal of the policies and procedures described in paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) REQUIREMENTS.—The policies, procedures, and guidance issued under this section shall describe the manner in which the Administrator shall ensure ~~that—~~ **that** —

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;

"(B) to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of

Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) Existing EPA Policies, Procedures, and Guidance.—The policies, procedures, and guidance described in subsection (b) shall incorporate, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.

"(e) Review.—Not later than 5 years after the date of enactment of this section, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(1) review the adequacy of any policies, procedures, and guidance developed under this section, including animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this Act; and

"(2) after providing public notice and an opportunity for comment, revise the policies, procedures, and guidance if necessary to reflect new scientific developments or understandings.

"(f) Sources of Information.—In making any decision with respect to a chemical substance under section 4, 4A, 5, or 6, the Administrator shall take into consideration information relating to the hazards and exposures of a chemical substance under the conditions of use that is reasonably available to the Administrator, including information that is—

"(1) submitted to the Administrator pursuant to any rule, consent agreement, order, or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act, by—

"(A) manufacturers or processors of a substance;

"(B) the public;

"(C) other Federal departments or agencies; or

"(D) the Governor of a State or a State agency with responsibility for protecting health or the environment;

"(2) submitted to a governmental entity in any jurisdiction pursuant to a governmental requirement relating to the protection of health or the environment; or

"(3) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible by the Administrator.

"(g) Testing of Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator shall establish policies and procedures for the testing of chemical substances or mixtures under section 4.

"(2) GOAL.—A goal of the policies and procedures established under paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) CONTENTS.—The policies and procedures established under paragraph (1) shall—

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition

that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential;

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations;

"(C) require the Administrator to consult with the Director of the National Institute for Occupational Safety and Health prior to prescribing epidemiologic studies of employees; and

"(D) prior to adopting a requirement for testing using vertebrate animals, require the Administrator to take into consideration, as appropriate and to the extent practicable, reasonably available—

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

"(iii) high-throughput screening methods and the prediction models of those methods; and

"(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.

~~"(4) Tiered testing.—~~

~~* 1 "(A) In general.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.~~

~~"(B) Screening-level tests.—~~

~~* 2 "(i) In general.—The screening-level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.~~

~~"(ii) Use.—Screening-level tests shall be used—~~

~~* 3 "(I) to screen chemical substances or mixtures for potential adverse effects; and~~

~~* 4 "(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.~~

~~* 5 "(C) Additional testing.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for safety assessments or~~

~~safety determinations, the Administrator may require more advanced tests for potential health or environmental effects or exposure potential.~~

~~* 6 "(D) Advanced testing without screening.—The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.~~

"(h) Safety Assessments and Safety Determinations.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(C) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall identify the substances subject to safety assessments and safety determinations to be completed that year.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(A) IN GENERAL.—The Administrator shall establish, by rule, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

"(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

"(C) MINIMUM REQUIREMENTS.—At a minimum, the policies and procedures under this paragraph shall—

"(i) describe—

"(I) the manner in which the Administrator will identify informational needs and seek that information from the public;

"(II) the information (including draft safety assessments) that may be submitted by interested individuals or entities, including States; and

"(III) the criteria by which that information will be evaluated;

"(ii) require the Administrator—

"(I)(aa) to define the scope of the safety assessment and safety determination to be conducted under section 6, including the hazards, exposures, conditions of use, and potentially exposed and susceptible populations that the Administrator expects to consider in a safety assessment;

"(bb) to explain the basis for the scope of the safety assessment and safety determination; and

"(cc) to accept comments regarding the scope of the safety assessment and safety determination; and

"(II)(aa) to identify the items described in subclause (I) that the Administrator has considered in the final safety assessment; and

"(bb) to explain the basis for the consideration of those items;

"(iii) describe the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the conditions of use will be considered, and explain the basis for that consideration in the final safety assessment;

"(iv) require that each safety assessment and safety determination shall include—

"(I) a description of the weight of the scientific evidence of risk; and

"(II) a summary of the information regarding the impact on health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies;

"(v) establish a timely and transparent process for evaluating whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination; and

"(vi) when relevant information is provided or otherwise made available to the Administrator, shall consider the extent of Federal regulation under other Federal laws.

"(D) GUIDANCE.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop guidance to assist interested persons in developing **their own** draft safety assessments and other information for submission to the Administrator, which may be considered at the discretion of the Administrator.

"(ii) REQUIREMENT.—The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing a draft assessment for consideration by the Administrator.

~~"(3) Articles.—If the Administrator intends to prohibit or otherwise restrict an article on the basis of a chemical substance contained in that article, the Administrator shall have evidence of significant exposure to the chemical substance from such article.~~

"(i) Publicly Available Information.—Subject to section 14, the Administrator shall—

"(1) make publicly available a nontechnical summary, and the final version, of each safety assessment and safety determination;

"(2) provide public notice and an opportunity for comment on each proposed safety assessment and safety determination; and

"(3) make public in a final safety assessment and safety determination—

"(A) the list of studies considered by the Administrator in carrying out the safety assessment or safety determination; and

"(B) the list of policies, procedures, and guidance that were followed in carrying out the safety assessment or safety determination.

"(j) Consultation With Science Advisory Committee on Chemicals.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish an advisory committee, to be known as the 'Science Advisory Committee on Chemicals' (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, on the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(5) RELATIONSHIP TO OTHER LAW.—All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).".

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) In General.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking subsections (a), (b), (c), (d), and (g);

(2) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively;

(3) in subsection (f) (as so redesignated)—

(A) by striking "rule" each place it appears and inserting "rule, testing consent agreement, or order";

(B) by striking "under subsection (a)" each place it appears and inserting "under this subsection"; and

(C) in paragraph (1)(B), in the last sentence, by striking "rulemaking";

(4) in subsection (g) (as so redesignated)—

(A) in the first sentence, by striking "from cancer, gene mutations, or birth defects"; and

(B) by striking the last sentence; and

(5) by inserting before subsection (f) (as so redesignated) the following:

"(a) Development of New Information on Chemical Substances and Mixtures.—

"(1) IN GENERAL.—The Administrator may require the development of new information relating to a chemical substance or mixture in accordance with this section if the Administrator determines that the information is necessary—

"(A) to review a notice under section 5(d) or to perform a safety assessment or safety determination under section 6;

"(B) to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4) or under a rule promulgated under section 6(d)(3);

"(C) pursuant to section 12(a)(4); or

"(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

"(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.

"(B) PROHIBITION.—Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.

"(C) LIMITATION.—The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

"(3) FORM.—Subject to section 3A(h), the Administrator may require the development of information described in paragraph (1) or (2) by—

"(A) promulgating a rule;

"(B) entering into a testing consent agreement; or

"(C) issuing an order.

"(4) CONTENTS.—

"(A) IN GENERAL.—A rule, testing consent agreement, or order issued under this subsection shall include—

"(i) identification of the chemical substance or mixture for which testing is required;

"(ii) identification of the persons required to conduct the testing;

"(iii) test protocols and methodologies for the development of test data and information for the chemical substance or mixture, including specific reference to reliable nonanimal test procedures; and

"(iv) specification of the period within which individuals and entities required to conduct the testing shall submit to the Administrator the information developed

in accordance with the procedures described in clause (iii).

"(B) CONSIDERATIONS.—In determining the procedures and period to be required under subparagraph (A), the Administrator shall take into consideration—

"(i) the relative costs of the various test protocols and methodologies that may be required; and

"(ii) the reasonably foreseeable availability of facilities and personnel required to perform the testing.

"(b) Statement of Need.—

"(1) IN GENERAL.—In promulgating a rule, entering into a testing consent agreement, or issuing an order for the development of additional information (including information on exposure or exposure potential) pursuant to this section, the Administrator shall—

"(A) identify the need intended to be met by the rule, agreement, or order;

"(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of vertebrate animals.

"(2) EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an order is warranted instead of promulgating a rule or entering into a testing consent agreement.

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a description of—

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

"(ii) the extent to which the Administrator has obtained or attempted to obtain the information through voluntary submissions; and

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) Reduction of Testing on Vertebrates.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while

providing information of high scientific quality;

"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reliable and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

"(I) animal-based studies; and

"(II) emerging methods and models; and

"(B) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) after providing an opportunity for public comment, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information under this title that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

"(C) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation; and

"(D) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing under this title.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical

substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(d) Testing Requirements.—

"(1) IN GENERAL.—The Administrator may require the development of information by—

"(A) manufacturers and processors of the chemical substance or mixture; and

"(B) **subject to paragraph (3),** persons that begin to manufacture or process the chemical substance or mixture—

"(i) after the effective date of the rule, testing consent agreement, or order; but

"(ii) ~~subject to paragraph (3),~~ before the period ending on the ~~date that is 180 days after the end of the period described in this section.~~ **later of—**

"(I) 5 years after the date referred to in clause (i); or

"(II) the last day of the period that begins on the date referred to in clause (i) and that is equal to the period that the Administrator determines was necessary to develop the information.

"(2) DESIGNATION.—The Administrator may permit 2 or more persons identified in subparagraph (A) or (B) of paragraph (1) to designate 1 of the persons or a qualified third party—

"(A) to develop the information; and

"(B) to submit the information on behalf of the persons making the designation.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—A person otherwise subject to a rule, testing consent agreement, or order under this section may submit to the Administrator an application for an exemption on the basis that the information is being developed by a person designated under paragraph (2).

"(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

"(i) IN GENERAL.—If the Administrator accepts an application submitted under subparagraph (A), the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as agreed to between the applicant and the designee.

"(ii) ARBITRATION.—If the applicant and a person designated under paragraph (2) cannot reach agreement on the amount of fair and equitable reimbursement, the amount shall be determined by arbitration.

"(C) TERMINATION.—If, after granting an exemption under this paragraph, the

Administrator determines that a person covered by the exemption has failed to comply with the rule, testing consent agreement, or order, the Administrator shall—

"(i) by order, terminate the exemption; and

"(ii) notify in writing each person that received an exemption of the requirements with respect to which the exemption was granted.

"(4) TIERED TESTING.—

** 1 "(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.

"(B) SCREENING-LEVEL TESTS.—

** 2 "(i) IN GENERAL.—The screening-level tests required for a chemical substance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.

"(ii) USE.—Screening-level tests shall be used—

** 3 "(I) to screen chemical substances or mixtures for potential adverse effects; and

** 4 "(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.

** 5 "(C) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for safety assessments or safety determinations, the Administrator may require more advanced tests for potential health or environmental effects or exposure potential.

** 6 "(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

"(e) Transparency.—Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders and all information submitted under this section.".

(b) Conforming Amendment.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the third sentence by striking "section 4(e)" and inserting "section 4(f)".

SEC. 6. PRIORITIZATION SCREENING.

The Toxic Substances Control Act is amended by inserting after section 4 (15 U.S.C. 2603) the following:

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) Establishment and List of Substances.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish, by rule, a risk-based screening process and explicit criteria for identifying existing chemical substances that are—

"(A) a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances'); and

"(B) a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').

"(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(A) IN GENERAL.—Before the date of promulgation of the rule under paragraph (1) and not later than 180 days after the date of enactment of this section, the Administrator—

"(i) shall take into consideration and publish an initial list of high-priority substances and low-priority substances; and

"(ii) pursuant to section 6(b), may initiate or continue safety assessments and safety determinations for those high-priority substances.

"(B) REQUIREMENTS.—

"(i) IN GENERAL.—The initial list of chemical substances shall contain at least 10 high-priority substances, at least 5 of which are drawn from the list of chemical substances identified by the Administrator in the October~~,~~ 2014 TSCA Work Plan and subsequent updates, and at least 10 low-priority substances.

"(ii) SUBSEQUENTLY IDENTIFIED SUBSTANCES.—Insofar as possible, at least 50 percent of all substances subsequently identified by the Administrator as high-priority substances shall be drawn from the list of chemical substances identified by the Administrator in the October~~,~~ 2014 TSCA Work Plan and subsequent updates, until all Work Plan chemicals have been designated under this subsection.

"(iii) PERSISTENCE AND BIOACCUMULATION.—In developing the initial list and in identifying additional high-priority substances, the Administrator shall give preference to chemical substances scored as high for persistence and bioaccumulation in the October 2014 TSCA Work Plan and subsequent updates.

"(C) ADDITIONAL CHEMICAL REVIEWS.—The Administrator ~~shall—~~ **shall, as soon as practicable—**

"(i) 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 20 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 20 low-priority substances have been designated; and

"(ii) ~~as soon as practicable and not later than~~ 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 25 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 25 low-priority substances have been designated.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator shall take into consideration active substances, as determined under section 8, which may include chemical substances on the interim list of active substances established under that section.

"(ii) INACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator may take into consideration inactive substances, as determined under section 8, that the Administrator determines—

"(I)(aa) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) have the potential for high hazard and widespread exposure; or

"(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) with respect to which there exists the potential for residual high hazards or widespread exposures not otherwise addressed by the regulatory or other action.

"(iii) REPOPULATION.—

"(I) IN GENERAL.—On the completion of a safety determination under section 6 for a chemical substance, the Administrator shall remove the chemical substance from the list of high-priority substances established under this subsection.

"(II) ADDITIONS.—The Administrator shall add at least 1 chemical substance to the list of high-priority substances for each chemical substance removed from the list of high-priority substances established under this subsection, until a safety assessment and safety determination is completed for all high-priority substances.

"(III) LOW-PRIORITY SUBSTANCES.—If a low-priority substance is subsequently designated as a high-priority substance, the Administrator shall remove that substance from the list of low-priority substances.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) not later than 180 days after the effective date of the final rule under paragraph (1), begin the prioritization screening process; and

"(II) make every effort to complete the designation of all active substances as high-priority substances or low-priority substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical substance as a high-priority substance or low-priority substance.

"(iii) CONSIDERATION.—

"(I) IN GENERAL.—The Administrator shall screen substances and designate high-priority substances taking into consideration the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in a timely manner.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.

"(C) SCREENING OF CATEGORIES OF SUBSTANCES.—The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate designations of high-priority substances and low-priority substances and safety assessments and safety determinations for high-priority substances.

"(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—Not less frequently than once each year, the Administrator shall publish a list of chemical substances that—

"(i) are being considered in the prioritization screening process and the status of the chemical substances in the prioritization process, including those chemical substances for which prioritization decisions have been deferred; and

"(ii) are designated as high-priority substances or low-priority substances, including the bases for such designations.

"(4) CRITERIA.—The criteria described in paragraph (1) shall account for—

"(A) the recommendation of the Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances appropriate for prioritization screening;

"(B) the hazard and exposure potential of the chemical substance (or category of substances), including **persistence, bioaccumulation, and** specific scientific classifications and designations by authoritative governmental entities;

"(C) the conditions of use or significant changes in the conditions of use of the chemical substance;

"(D) evidence and indicators of exposure potential to humans or the environment from the chemical substance, including potentially exposed or susceptible populations;

"(E) the volume of a chemical substance manufactured or processed;

"(F) whether the volume of a chemical substance as reported under a rule

promulgated pursuant to section 8(a) has significantly increased or decreased during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance;

"(G) the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

"(H) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a **high-priority or a** low-priority substance.

"(b) Prioritization Screening Process and Decisions.—

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall include a requirement that the Administrator shall—

"(A) identify the chemical substances being considered for prioritization;

"(B) request interested persons to supply information regarding the chemical substances being considered;

"(C) apply the criteria identified in subsection (a)(4); and

"(D) subject to paragraph (5) and using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.

"(2) INTEGRATION OF INFORMATION.—The prioritization screening decision regarding a chemical substance shall integrate any hazard and exposure information relating to the chemical substance that is available to the Administrator.

"(3) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(A) shall identify as a high-priority substance a chemical substance that, relative to other **active** chemical substances, the Administrator determines has the potential for high hazard and widespread exposure;

"(B) may identify as a high-priority substance a chemical substance that, relative to other **active** chemical substances, the Administrator determines has the potential for high hazard or widespread exposure; and

"(C) may identify as a high-priority substance an inactive substance, as determined under subsection (a)(3)(A)(ii) and section 8(b), that the Administrator determines warrants a safety assessment and safety determination under section 6.

"(4) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that the chemical substance is likely to meet the ~~applicable~~ safety standard.

"(5) DEFERRING A DECISION.—If the Administrator determines that additional information is required to establish the priority of a chemical substance under this section, the Administrator may defer the prioritization screening decision for a reasonable period—

"(A) to allow for the submission of additional information by an interested person and for the Administrator to evaluate the additional information; or

"(B) to require the development of information pursuant to a rule, testing consent agreement, or order issued under section 4(a)(2).

"(6) DEADLINES FOR SUBMISSION OF INFORMATION.—If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of the information.

"(7) NOTICE AND COMMENT.—The Administrator shall—

"(A) publish the proposed decisions made under paragraphs (3), (4), and (5) and the basis for the decisions; and

"(B) provide an opportunity for public comment.

"(8) REVISIONS OF PRIOR DESIGNATIONS.—

"(A) IN GENERAL.—At any time, and at the discretion of the Administrator, the Administrator may revise the designation of a chemical substance as a high-priority substance or a low-priority substance based on information available to the Administrator after the date of the determination under paragraph (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.

"(9) OTHER INFORMATION RELEVANT TO PRIORITIZATION.—

"(A) IN GENERAL.—If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State proposes an administrative action or enacts a statute or takes an administrative action to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not as designated a high-priority substance, the Governor or State agency with responsibility for implementing the statute or administrative action shall notify the Administrator.

"(B) REQUESTS FOR INFORMATION.—Following receipt of a notification provided under subparagraph (A), the Administrator may request any available information from the Governor or the State agency with respect to—

"(i) scientific evidence related to the hazards, exposures and risks of the chemical substance under the conditions of use which the statute or administrative action is intended to address;

"(ii) any State or local conditions which warranted the statute or administrative action;

"(iii) the statutory or administrative authority on which the action is based; and

"(iv) any other available information relevant to the prohibition or other restriction, including information on any alternatives considered and their hazards, exposures, and risks.

"(C) PRIORITIZATION SCREENING.—The Administrator shall conduct a prioritization screening under this subsection for all substances that—

"(i) are the subject of notifications received under subparagraph (A); and

"(ii) the Administrator determines—

"(I) are likely to have significant health or environmental impacts;

"(II) are likely to have significant impact on interstate commerce; or

"(III) have been subject to a prohibition or other restriction under a statute or administrative action in 2 or more States.

"(D) AVAILABILITY TO PUBLIC.—Subject to section 14 and any applicable State law regarding the protection of confidential information provided to the State or to the Administrator, the Administrator shall make information received from a Governor or State agency under subparagraph (A) publicly available.

"(E) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall preempt a State statute or administrative action, require approval of a State statute or administrative action, or apply section 15 to a State.

"(10) REVIEW.—Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Administrator shall—

"(A) review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and

"(B) if necessary, modify the prioritization screening process.

"(11) EFFECT.—Subject to section 18, a designation by the Administrator under this section with respect to a chemical substance shall not affect—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance; or

"(B) the regulation of those activities.

"(c) Additional Priorities for Safety Assessments and Determinations.—

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall—

"(A) include a process by which a manufacturer or processor of an active chemical substance that has not been designated a high-priority substance~~, or that has not been subject to~~ or is not in the process of a prioritization screening by the Administrator, may request that the Administrator designate the substance **as an additional priority** for a safety assessment and safety determination, subject to the payment of fees pursuant to section 26(b)(3)(E);

~~and~~

~~"(B) provide guidance to submitters on~~**"(B) specify** the information to be provided in such requests~~,~~**;** and

"(C) specify the criteria the Administrator shall use to determine whether or not to grant such a request, which shall include whether the substance is subject to restrictions imposed by statutes enacted or administrative actions taken by 1 or more States on the manufacture, processing, distribution in commerce, or use of the substance.

"(2) PREFERENCE.—Subject to paragraph (3), in deciding whether to grant requests under this subsection the Administrator shall give a preference to requests concerning substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

"(3) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

"(A) not more than 15 percent of the total number of substances designated to undergo safety assessments and safety determinations under this section are substances designated under the process and criteria pursuant to paragraph (1); and

"(B) the resources allocated to conducting safety assessments and safety determinations for additional priorities designated under this subsection are proportionate to the number of such substances relative to the total number of substances designated to undergo safety assessments and safety determinations under this section.

"(4) REQUIREMENTS.—

"(A) IN GENERAL.—The public shall be provided notice and an opportunity to comment on requests submitted under this subsection.

"(B) DECISION BY ADMINISTRATOR.—Not later than 180 days after the date on which the Administrator receives a request under this subsection, the Administrator shall decide whether or not to grant the request.

"(C) ASSESSMENT AND DETERMINATION.—If the Administrator grants a request under this subsection, the safety assessment and safety determination—

"(i) shall be conducted in accordance with the deadlines and other requirements of sections 3A(i) and 6; and

"(ii) shall not be expedited or otherwise subject to special treatment relative to high-priority substances designated pursuant to subsection (b)(3) that are undergoing safety assessments and safety determinations.

"(5) EXCEPTIONS.—Requests granted under this subsection shall not be subject to subsection (a)(3)(A)(iii) or section 18(b).".

SEC. 7. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.";

(2) by striking subsection (b);

(3) by redesignating subsection (a) as subsection (b);

(4) by redesignating subsection (i) as subsection (a) and moving the subsection so as to appear at the beginning of the section;

(5) in subsection (b) (as so redesignated)—

(A) in the subsection heading, by striking "In General" and inserting "Notices"; and

(B) in paragraph (1), in the matter following subparagraph (B)—

(i) by striking "subsection (d)" and inserting "subsection (b)"; and

(ii) by striking "and such person complies with any applicable requirement of subsection (b)";

(6) by redesignating subsections (c) and (d) as subsection (d) and (c), respectively, and moving subsection (c) (as so redesigned) so as appear after subsection (b) (as redesignated by paragraph (3));

(7) in subsection (c) (as so redesignated)—

(A) by striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—The notice required by subsection (a) shall include, with respect to a chemical substance—

"(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

"(B) information regarding conditions of use and reasonably anticipated exposures.";

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking "or of data under subsection (b)";

(ii) in subparagraph (A), by adding "and" after the semicolon at the end;

(iii) in subparagraph (B), by striking "; and" and inserting a period; and

(iv) by striking subparagraph (C); and

(C) in paragraph (3), by striking "subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "subsection (b) and for which the notification period prescribed by subsection (b) or (d)";

(8) by striking subsection (d) (as redesignated by paragraph (6)) and inserting the

following:

"(d) Review of Notice.—

"(1) INITIAL REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall—

"(i) conduct an initial review of the notice;

"(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

"(iii) make any necessary determination under paragraph (3).

"(B) EXTENSION.—Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.

"(2) INFORMATION SOURCES.—In evaluating a notice under paragraph (1), the Administrator shall take into consideration—

"(A) any relevant information identified in subsection (c)(1); and

"(B) any other relevant additional information available to the Administrator.

"(3) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), based on the information described in paragraph (2), and subject to section 18(g), the Administrator shall determine that—

"(A) the relevant chemical substance or significant new use is not likely to meet the safety standard, in which case the Administrator shall take appropriate action under paragraph (4);

"(B) the relevant chemical substance or significant new use is likely to meet the safety standard, in which case the Administrator shall allow the review period to expire without additional restrictions; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (5).

"(4) RESTRICTIONS.—

"(A) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—If the Administrator makes a determination under subparagraph (A) or (C) of paragraph (3) with respect to a notice submitted under subsection (b)—

"(I) the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, as appropriate, shall prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the restrictions specified in the consent agreement or order that the

Administrator determines are sufficient to ensure that the chemical substance or significant new use is likely to meet the safety standard; and

"(II) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, except in compliance with the restrictions specified in the consent agreement or order.

"(ii) LIKELY TO MEET STANDARD.—If the Administrator makes a determination under subparagraph (B) of paragraph (3) with respect to a chemical substance or significant new use for which a notice was submitted under subsection (b), at the end of the applicable period for review under paragraph (1), the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use.

"(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall—

"(i) take into consideration whether to promulgate a rule pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance, or of the chemical substance for a new use, that is not in compliance with the restrictions imposed by the consent agreement or order; and

"(ii)(I) initiate a rulemaking described in clause (i); or

"(II) publish a statement describing the reasons of the Administrator for not initiating a rulemaking.

"(C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include, as appropriate—

"(i) subject to section 18(g), a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator;

"(ii) a requirement that manufacturers or processors of the chemical substance shall—

"(I) make and retain records of the processes used to manufacture or process, as applicable, the chemical substance; or

"(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, use, or disposal, as applicable, of the chemical substance, subject to section 4;

"(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

"(I) in general; or

"(II) for a particular use;

"(iv) a prohibition or other restriction of—

"(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

"(II) any method of commercial use of the chemical substance; or

"(III) any method of disposal of the chemical substance; or

"(v) a prohibition or other restriction on the manufacture, processing, or distribution in commerce of the chemical substance—

"(I) in general; or

"(II) for a particular use.

"(D) **MITIGATION.—In selecting among prohibitions and restrictions to address an identified potential risk, the Administrator shall apply prohibitions or restrictions to articles on the basis of a chemical substance or mixture contained in the article only to the extent necessary to mitigate the identified potential risk.**

"(E) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction under this subsection to address workplace exposures.

~~"(E)~~**"(F)** DEFINITION OF REQUIREMENT.—For purposes of this Act, the term 'requirement' as used in this section does not displace common law.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

"(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(C) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

"(D) on receipt of information the Administrator finds supports the determination under paragraph (3), shall promptly make the determination.";

(9) by striking subsections (e) through (g) and inserting the following:

"(e) Notice of Commencement.—

"(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—

"(A) the name of the manufacturer; and

"(B) the initial date of nonexempt commercial manufacture.

"(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

"(f) Further Evaluation.—The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—

"(1) a notice of commencement for a chemical substance under subsection (c); or

"(2) new information regarding the chemical substance.

"(g) Transparency.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, consent agreements, rules, and orders of the Administrator; and

"(2) all information submitted or issued under this section."; and

(10) in subsection (h)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking "(a) or";

(B) by striking paragraph (2);

(C) by redesignating paragraphs (3) through (6) as paragraphs (2) through (5), respectively;

(D) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking "subsections (a) and (b)" and inserting "subsection (b)";

(E) in paragraph (3) (as so redesignated)—

(i) in the first sentence, by striking "will not present an unreasonable risk of injury to health or the environment" and inserting "will meet the safety standard"; and

(ii) by striking the second sentence;

(F) in paragraph (4) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (b)"; and

(G) in paragraph (5) (as so redesignated), in the first sentence, by striking "paragraph (1) or (5)" and inserting "paragraph (1) or (4)".

SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections (g) and (h), respectively;

(3) by striking subsections (a) through (d) and inserting the following:

"(a) In General.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) shall, as soon as practicable and not later than 6 months after the date on which a chemical substance is designated as a high-priority substance, define the scope of the safety assessment and safety determination to be conducted pursuant to this section, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that the Administrator expects to consider;

"(3) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(4) shall complete a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

"(5) shall promulgate a final rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; and

"(6) may extend any deadline under this subsection for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under paragraphs (4) and (5) and any deferral under subsection (c)(2) does not exceed 2 years.

"(b) Prior Actions.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination that was initiated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, prior to the effective date of the policies and procedures required to be established by the Administrator under section 3A or 4A.

"(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or rule solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the validity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure.

"(c) Safety Determinations.—

"(1) IN GENERAL.—Based on a review of the information available to the Administrator,

including draft safety assessments submitted by interested persons, and subject to section 18, the Administrator shall determine that—

"(A) the relevant chemical substance meets the safety standard;

"(B) the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by rule under subsection (d)—

"(i) impose restrictions necessary to ensure that the chemical substance meets the safety standard under the conditions of use; or

"(ii) if the safety standard cannot be met with the application of restrictions, ban or phase out the chemical substance, as appropriate; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is necessary to make a safety assessment or safety determination for a high-priority substance, the Administrator—

"(A) shall provide an opportunity for interested persons to submit the additional information;

"(B) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

"(C) may defer, for a reasonable period consistent with the deadlines described in subsection (a), a safety assessment and safety determination until after receipt of the information; and

"(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety determination, shall make a determination under paragraph (1).

"(3) ESTABLISHMENT OF DEADLINE.—In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.

"(d) Rule.—

"(1) IMPLEMENTATION.—If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a rule establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

"(2) ~~SCOPE.—THE~~ **SCOPE.—**

"(A) IN GENERAL.—The rule promulgated pursuant to this subsection—

~~"(A) may—~~

"(i) **may** apply to mixtures containing the chemical substance, as appropriate;

~~and~~

~~"(ii) exempt replacement parts for articles manufactured prior to the applicable compliance deadline; and~~

~~"(B)~~**"(ii)** shall include dates by which compliance is mandatory, which—

~~"(i)~~**"(I)** shall be as soon as practicable; and

~~"(ii)~~**"(II)** as determined by the Administrator, may vary for different affected persons**; and**.

~~"(C)~~**"(iii) shall—**

"(I) exempt replacement parts that are manufactured prior to the effective date of the rule for articles that are first manufactured prior to the effective date of the rule unless the Administrator finds the replacement parts contribute significantly to the identified risk; and

"(II) in selecting among prohibitions and restrictions to address an identified risk, apply prohibitions or restrictions to articles on the basis of a chemical substance or mixture contained in the article only to the extent necessary to mitigate the identified risk.

"(B) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or other restriction under this subsection to address workplace exposures.

~~"(D)~~**"(C)** DEFINITION OF REQUIREMENT.—For the purposes of this Act, the term 'requirement' as used in this section does not displace common law.

"(3) RESTRICTIONS.—A restriction under paragraph (1) may include, as appropriate—

"(A) subject to section 18, a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator;

"(B) a requirement that manufacturers or processors of the chemical substance shall—

"(i) make and retain records of the processes used to manufacture or process the chemical substance;

"(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or

"(iii) monitor or conduct tests that are reasonably necessary to ensure compliance with the requirements of any rule under this subsection;

"(C) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

"(D) a requirement to ban or phase out, or any other rule regarding, the manufacture, processing, or distribution in commerce of the chemical substance for—

"(i) a particular use;

"(ii) a particular use at a concentration in excess of a level specified by the Administrator; or

"(iii) all uses;

"(E) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—

"(i) a particular use; or

"(ii) a particular use at a concentration in excess of a level specified by the Administrator;

"(F) a requirement to ban, phase out, or otherwise restrict any method of commercial use of the chemical substance;

"(G) a requirement to ban, phase out, or otherwise restrict any method of disposal of the chemical substance or any article containing the chemical substance; and

"(H) a requirement directing manufacturers or processors of the chemical substance to give notice of the Administrator's determination under subsection (c)(1)(B) to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1 or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

"(5) EXEMPTIONS.—

"(A) IN GENERAL.—The Administrator may exempt 1 or more uses of a chemical substance from any restriction in a rule promulgated under paragraph (1) if the Administrator determines that—

"(i) the rule cannot be complied with, without—

"(I) harming national security;

"(II) causing significant disruption in the national economy due to the lack of availability of a chemical substance; or

"(III) interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or

"(ii) the use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

"(B) EXEMPTION ANALYSIS.—In proposing a rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall make publicly available any analysis conducted under this paragraph to assess the need for the exemption.

"(C) STATEMENT REQUIRED.—In making final a rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall include a statement describing how the analysis considered under subparagraph (B) was taken into account.

"(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—In determining whether an exemption should be granted under this paragraph for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more technically and economically feasible alternatives to the chemical substance most likely to be used in place of the chemical substance under the conditions of use if the rule is promulgated.

"(E) CONDITIONS.—As part of a rule promulgated under paragraph (1), the Administrator shall include conditions in any exemption established under this paragraph, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption.

"(F) DURATION.—

"(i) IN GENERAL.—The Administrator shall establish, as part of a rule under paragraph (1) that contains an exemption under this paragraph, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis.

"(ii) AUTHORITY OF ADMINISTRATOR.—The Administrator, by rule, may extend, modify, or eliminate the exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or is no longer necessary.

"(iii) CONSIDERATIONS.—

"(I) IN GENERAL.—Subject to subclause (II), the Administrator shall issue exemptions and establish time periods by considering factors determined by

the Administrator to be relevant to the goals of fostering innovation and the development of alternatives that meet the safety standard.

"(II) LIMITATION.—Any renewal of an exemption in the case of a rule requiring the ban or phase-out of a chemical substance shall not exceed 5 years.

"(e) Immediate Effect.—The Administrator may declare a proposed rule under subsection (d)**(1)** to be effective on publication of the rule in the Federal Register and until the effective date of final action taken respecting the rule, if—

"(1) the Administrator determines that—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to the proposed rule or any combination of those activities is likely to result in an unreasonable risk of serious or widespread harm to health or the environment before the effective date; and

"(B) making the proposed rule so effective is necessary to protect the public interest; and

"(2) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under paragraph (1)(A), a court has granted relief in an action under section 7 with respect to that risk associated with the chemical substance or mixture.

"(f) Final Agency Action.—Under this section and subject to section 18—

"(1) a safety determination, and the associated safety assessment, for a chemical substance that the Administrator determines under subsection (c) meets the safety standard, shall be considered to be a final agency action, effective beginning on the date of issuance of the final safety determination; and

"(2) a final rule promulgated under subsection (d)**(1)**, and the associated safety assessment and safety determination that a chemical substance does not meet the safety standard, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule."; and

(4) in subsection (g) (as redesignated by paragraph (2))—

(A) by striking paragraph (4); and

(B) by redesignating paragraph (5) as paragraph (4).

SEC. 9. IMMINENT HAZARDS.

Section 7 of the Toxic Substances Control Act (15 U.S.C. 2606) is amended—

(1) by striking subsection (a) and inserting the following:

"(a) Civil Actions.—

"(1) IN GENERAL.—The Administrator may commence a civil action in an appropriate United States district court for—

"(A) seizure of an imminently hazardous chemical substance or mixture or any

article containing the chemical substance or mixture;

"(B) relief (as authorized by subsection (b)) against any person that manufactures, processes, distributes in commerce, uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing the chemical substance or mixture; or

"(C) both seizure described in subparagraph (A) and relief described in subparagraph (B).

"(2) RULE, ORDER, OR OTHER PROCEEDING.—A civil action may be commenced under this paragraph, notwithstanding—

"(A) the existence of—

"(i) a decision by the Administrator under section 4A, 5(d)(3), or 6(c)(1); or

"(ii) a rule, testing consent agreement, or order under section 4, 5(d)(4), 6(d), or 6(h); or

"(B) the pendency of any administrative or judicial proceeding under any provision of this Act.";

(2) in subsection (d), by striking "section 6(a)" and inserting "section 6(c)"; and

(3) in subsection (f), in the first sentence, by striking "and unreasonable".

SEC. 10. INFORMATION COLLECTION AND REPORTING.

Section 8 of the Toxic Substances Control Act (15 U.S.C. 2607) is amended—

(1) in subsection (a)—

(A) in paragraph (3)(A)(ii)(I)—

(i) by striking "5(b)(4)" and inserting "5";

(ii) by inserting "section 4 or" after "in effect under"; and

(iii) by striking "5(e)," and inserting "5(d)(4);"; and

(B) by adding at the end the following:

"(4) RULES.—

"(A) DEADLINE.—

"(i) IN GENERAL.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall promulgate rules requiring the maintenance of records and the reporting of information known or reasonably ascertainable by the person making the report, including rules requiring processors to report information, so that the Administrator has the information necessary to carry out sections 4 and 6.

"(ii) MODIFICATION OF PRIOR RULES.—In carrying out this subparagraph, the Administrator may modify, as appropriate, rules promulgated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(B) CONTENTS.—The rules promulgated pursuant to subparagraph (A)—

"(i) may impose different reporting and recordkeeping requirements on manufacturers and processors; and

"(ii) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported.

"(C) ADMINISTRATION.—In implementing the reporting and recordkeeping requirements under this paragraph, the Administrator shall take measures—

"(i) to limit the potential for duplication in reporting requirements;

"(ii) to minimize the impact of the rules on small manufacturers and processors; and

"(iii) to apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title.

"(5) GUIDANCE.—The Administrator shall develop guidance relating to the information required to be reported under the rules promulgated under this subsection.";

(2) in subsection (b), by adding at the end the following:

"(3) NOMENCLATURE.—

"(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

"(i) maintain the use of Class 2 nomenclature in use on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled 'Candidate List of Chemical Substances', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

"(iii) treat all components of categories that are considered to be statutory mixtures under this Act as being included on the list published under paragraph (1) under the Chemical Abstracts Service numbers for the respective categories, including, without limitation—

"(I) cement, Portland, chemicals, CAS No. 65997–15–1;

"(II) cement, alumina, chemicals, CAS No. 65997–16–2;

"(III) glass, oxide, chemicals, CAS No. 65997–17–3;

"(IV) frits, chemicals, CAS No. 65997–18–4;

"(V) steel manufacture, chemicals, CAS No. 65997–19–5; and

"(VI) ceramic materials and wares, chemicals, CAS No. 66402–68–4.

"(B) MULTIPLE NOMENCLATURE CONVENTIONS.—

"(i) IN GENERAL.—If an existing guidance allows for multiple nomenclature

conventions, the Administrator shall—

"(I) maintain the nomenclature conventions for substances; and

"(II) develop new guidance that—

"(aa) establishes equivalency between the nomenclature conventions for chemical substances on the list published under paragraph (1); and

"(bb) permits persons to rely on the new guidance for purposes of determining whether a chemical substance is on the list published under paragraph (1).

"(ii) MULTIPLE CAS NUMBERS.—For any chemical substance appearing multiple times on the list under different Chemical Abstracts Service numbers, the Administrator shall develop guidance recognizing the multiple listings as a single chemical substance.

"(4) CHEMICAL SUBSTANCES IN COMMERCE.—

"(A) RULES.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator, by rule, shall require manufacturers and processors to notify the Administrator, by not later than 180 days after the date of promulgation of the rule, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

"(ii) ACTIVE SUBSTANCES.—The Administrator shall, pursuant to paragraph (5)(A), designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

"(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—The rule promulgated by the Administrator pursuant to subparagraph (A) shall require—

"(i) the Administrator to maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14;

"(ii) a manufacturer or processor that is submitting a notice pursuant to subparagraph (A) for a chemical substance on the confidential portion of the list published under paragraph (1) to indicate in the notice whether the manufacturer or processor seeks to maintain any existing claim for protection against disclosure of the specific identity of the substance as confidential pursuant to section 14; and

"(iii) the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph (C).

"(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the

Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the list published under paragraph (1) that are notified pursuant to subparagraph (A) or identified as active substances under subsection (f)(1).

"(D) REQUIREMENTS OF REVIEW PLAN.—The review plan under subparagraph (C) shall—

"(i) require, at the time requested by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the date of the request by the Administrator;

"(ii) require the Administrator, in accordance with section 14—

"(I) to review each substantiation—

"(aa) submitted pursuant to clause (i) to determine if the claim warrants protection from disclosure; and

"(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

"(II) approve, modify, or deny each claim; and

"(III) except as provided in this section and section 14, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(iii) encourage manufacturers or processors that have previously made claims to protect the specific identities of chemical substances identified as inactive pursuant to subsection (f)(2) to review and either withdraw or substantiate the claims.

"(E) TIMELINE FOR COMPLETION OF REVIEWS.—

"(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

"(ii) CONSIDERATIONS.—

"(I) IN GENERAL.—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of applicable claims needing review and the available resources.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of reviews to be completed over the course of implementation of the plan.

"(5) ACTIVE AND INACTIVE SUBSTANCES.—

"(A) IN GENERAL.—The Administrator shall maintain and keep current designations of active substances and inactive substances on the list published under paragraph (1).

"(B) UPDATE.—The Administrator shall update the list of chemical substances designated as active substances as soon as practicable after the date of publication of the most recent data reported under—

"(i) part 711 of title 40, Code of Federal Regulations (or successor regulations); and

"(ii) the rules promulgated pursuant to subsection (a)(4).

"(C) CHANGE TO ACTIVE STATUS.—

"(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

"(ii) CONFIDENTIAL CHEMICAL IDENTITY CLAIMS.—If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific identity of the inactive substance as confidential, the person shall—

"(I) in the notice submitted under clause (i), assert the claim; and

"(II) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

"(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

"(I) designate the applicable chemical substance as an active substance;

"(II) pursuant to section 14, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific identity of the chemical substance and approve, modify, or deny the claim;

"(III) except as provided in this section and section 14, protect from disclosure the specific identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of not less

than 10 years, unless, prior to the expiration of the period—

"(aa) the person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(bb) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in section 14(g)(2); and

"(IV) pursuant to section 4A, review the priority of the chemical substance as the Administrator determines to be necessary.

"(D) CATEGORY STATUS.—The list of inactive substances shall not be considered to be a category for purposes of section 26(c).

"(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the rule required under this subsection, the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (or successor regulations), during the reporting period that most closely preceded the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as the interim list of active substances for the purposes of section 4A.

"(7) PUBLIC PARTICIPATION.—Subject to this subsection, the Administrator shall make available to the public—

"(A) the specific identity of each chemical substance on the nonconfidential portion of the list published under paragraph (1) that the Administrator has designated as—

"(i) an active substance; or

"(ii) an inactive substance;

"(B) the accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received and approved by the Administrator pursuant to section 14; and

"(C) subject to section 14(g), the specific identity of any active substance for which—

"(i) no claim of protection against disclosure of the specific identity of the active substance pursuant to this subsection was received;

"(ii) a claim for protection against disclosure of the specific identity of the active substance has been denied by the Administrator; or

"(iii) the time period for protection against disclosure of the specific identity of the active substance has expired.

"(8) LIMITATION.—No person may assert a new claim under this subsection for protection from disclosure of a specific identity of any active or inactive chemical substance for which a notice is received under paragraph (4)(A)(i) or (5)(C)(i) that is not on the confidential portion of the list published under paragraph (1).

"(9) CERTIFICATION.—Under the rule promulgated under this subsection, manufacturers and processors shall be required—

"(A) to certify that each report the manufacturer or processor submits complies with the requirements of the rule, and that any confidentiality claims are true and correct; and

"(B) to retain a record supporting the certification for a period of 5 years beginning on the last day of the submission period.";

(3) in subsection (e)—

(A) by striking "Any person" and inserting the following:

"(1) IN GENERAL.—Any person"; and

(B) by adding at the end the following:

"(2) APPLICABILITY.—Any person may submit to the Administrator information reasonably supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of harm to health and the environment."; and

(4) in subsection (f), by striking "For purposes of this section, the" and inserting the following: "In this section:

"(1) ACTIVE SUBSTANCE.—The term 'active substance' means a chemical substance—

"(A) that has been manufactured or processed for a nonexempt commercial purpose at any point during the 10-year period ending on the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act;

"(B) that is added to the list published under subsection (b)(1) after that date of enactment; or

"(C) for which a notice is received under subsection (b)(5)(C).

"(2) INACTIVE SUBSTANCE.—The term 'inactive substance' means a chemical substance on the list published under subsection (b)(1) that does not meet any of the criteria described in paragraph (1).

"(3) MANUFACTURE; PROCESS.—The".

SEC. 11. RELATIONSHIP TO OTHER FEDERAL LAWS.

Section 9 of the Toxic Substances Control Act (15 U.S.C. 2608) is amended—

(1) in subsection (a)—

(A) in paragraph (1), in the first sentence—

(i) by striking "presents or will present an unreasonable risk to health or the environment" and inserting "does not meet the safety standard"; and

(ii) by striking "such risk" the first place it appears and inserting "the risk posed by the substance or mixture";

(B) in paragraph (2), in the matter following subparagraph (B), by striking "section 6 or 7" and inserting "section 6(d) or section 7"; and

(C) in paragraph (3), by striking "section 6 or 7" and inserting "section 6(d) or 7";

(2) in subsection (d), in the first sentence, by striking "Health, Education, and Welfare" and inserting "Health and Human Services"; and

(3) by adding at the end the following:

"(e) Exposure Information.—If the Administrator obtains information related to exposures or releases of a chemical substance that may be prevented or reduced under another Federal law, including laws not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.".

SEC. 12. RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA.

Section 10 of the Toxic Substances Control Act (15 U.S.C. 2609) is amended by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services".

SEC. 13. EXPORTS.

Section 12 of the Toxic Substances Control Act (15 U.S.C. 2611) is amended—

(1) in subsection (a), by striking paragraph (2) and inserting the following:

"(2) EXCEPTION.—Paragraph (1) shall not apply to any chemical substance that the Administrator determines—

"(A) under section 5 is not likely to meet the safety standard; or

"(B) under section 6 does not meet the safety standard.

"(3) WAIVERS.—For a mixture or article containing a chemical substance described in paragraph (2), the Administrator may—

"(A) determine that paragraph (1) shall not apply to the mixture or article; or

"(B) establish a threshold concentration in a mixture or article at which paragraph (1) shall not apply.

"(4) TESTING.—The Administrator may require testing under section 4 of any chemical substance or mixture exempted from this Act under paragraph (1) for the purpose of determining whether the chemical substance or mixture meets the safety standard within the United States.";

(2) by striking subsection (b) and inserting the following:

"(b) Notice.—

"(1) IN GENERAL.—A person shall notify the Administrator that the person is exporting or intends to export to a foreign country—

"(A) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 5 is not likely to meet the safety standard and for which a prohibition or other restriction has been proposed or established under

that section;

"(B) a chemical substance or a mixture containing a chemical substance that the Administrator has determined under section 6 does not meet the safety standard and for which a prohibition or other restriction has been proposed or established under that section;

"(C) a chemical substance for which the United States is obligated by treaty to provide export notification;

"(D) a chemical substance or mixture subject to a prohibition or other restriction pursuant to a rule, order, or consent agreement in effect under this Act; or

"(E) a chemical substance or mixture for which the submission of information is required under section 4.

"(2) RULES.—

"(A) IN GENERAL.—The Administrator shall promulgate rules to carry out paragraph (1).

"(B) CONTENTS.—The rules promulgated pursuant to subparagraph (A) shall—

"(i) include such exemptions as the Administrator determines to be appropriate, which may include exemptions identified under section 5(h); and

"(ii) indicate whether, or to what extent, the rules apply to articles containing a chemical substance or mixture described in paragraph (1).

"(3) NOTIFICATION.—The Administrator shall submit to the government of each country to which a chemical substance or mixture is exported—

"(A) for a chemical substance or mixture described in subparagraph (A), (B), or (D) of paragraph (1), a notice of the determination, rule, order, consent agreement, requirement, or designation;

"(B) for a chemical substance described in paragraph (1)(C), a notice that satisfies the obligation of the United States under the applicable treaty; and

"(C) for a chemical substance or mixture described in paragraph (1)(E), a notice of availability of the information on the chemical substance or mixture submitted to the Administrator."; and

(3) in subsection (c)—

(A) by striking paragraph (3); and

(B) by redesignating paragraphs (4) through (6) as paragraphs (3) through (5), respectively.

SEC. 14~~. IMPORTS.~~

~~Section 13 of the Toxic Substances Control Act (15 U.S.C. 2612) is amended to read as follows:~~

~~"SEC. 13. IMPORTS.~~

~~"(a) Refusal of Entry.—~~

~~"(1) In general.—The Secretary of Homeland Security shall refuse entry into the customs territory of the United States (as defined in general note 2 to the Harmonized Tariff Schedule of the United States) any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry, if—~~

~~"(A) the Administrator—~~

~~"(i) has determined under section 6(c) that the chemical substance or mixture does not meet the safety standard; and~~

~~"(ii) has promulgated a rule pursuant to section 6(d) banning the chemical substance or mixture, as of the effective date of the rule;~~

~~"(B) the chemical substance—~~

~~"(i) is not included on the list under section 8(b)(1); and~~

~~"(ii) is not exempt from any requirement to be included on that list by this title or a rule promulgated by the Administrator pursuant to this title; or~~

~~"(C) the chemical substance, mixture, or any article containing the chemical substance or mixture is offered for entry in violation of—~~

~~"(i) a rule, consent agreement, or order in effect under this Act; or~~

~~"(ii) an order issued in a civil action brought under section 7 or title IV.~~

~~"(2) Procedure.—~~

~~"(A) In general.—Subject to subparagraph (B), if a chemical substance, mixture, or article containing a chemical substance or mixture is refused entry under paragraph (1), the Secretary of Homeland Security—~~

~~"(i) shall notify the consignee of the entry of the refusal;~~

~~"(ii) shall not release the chemical substance or mixture to the consignee; and~~

~~"(iii) shall cause the disposal or storage of the chemical substance or mixture under such rules as the Secretary may prescribe, if the chemical substance or mixture has not been exported by the consignee during the 90-day period beginning on the date of receipt of the notice of the refused entry.~~

~~"(B) Exception.—~~

~~"(i) In general.—The Secretary of Homeland Security, pending a review by the Administrator, may release to the consignee the chemical substance or mixture if the consignee—~~

~~"(I) executes a bond for the amount of the full invoice of the chemical substance or mixture (as set forth in the customs entry); and~~

~~"(II) pays a duty on the chemical substance or mixture.~~

~~"(ii) Administration.—If a consignee fails to return a chemical substance or mixture released to that consignee under clause (i) for any cause to the custody of the Secretary of Homeland Security on demand, the consignee shall be liable to the United States for liquidated damages equal to the full amount of the bond executed under clause (i)(I).~~

~~"(C) Storage.—All charges for storage, cartage, and labor on or for the disposal of a chemical substance or mixture that is~~

refused entry or released under this subsection shall be paid by the owner or consignee, and a default on that payment shall constitute a lien against any future entry made by the owner or consignee.

"(b) Certification.—

"(1) In general.—A person offering a chemical substance or mixture subject to this Act for entry into the customs territory of the United States shall certify to the Secretary of Homeland Security that—

"(A) after reasonable inquiry and to the best knowledge and belief of the person, the chemical substance or mixture is in compliance with any applicable rule, consent agreement, or order under section 5 or 6; and

"(B) the chemical substance—

"(i) is included on the list under section 8(b)(1); or

"(ii) is exempt from any requirement to be included on that list by this title or a rule promulgated by the Administrator pursuant to this title.

"(2) Articles.—

"(A) In general.—The Administrator, by rule, may require certification under paragraph (1) for an article containing a chemical substance or mixture that is subject to rule under section 5 or 6.

"(B) Requirement.—The rule under subparagraph (A) shall identify, with reasonable specificity, the types of articles, including parts or components of articles, that will be subject to the certification requirement.

"(C) Factors for consideration.—In determining the need for and

~~content of a certification rule under this paragraph, the Administrator shall take into consideration—~~

~~"(i) the utility of the certification to enforcement of the applicable rule, consent agreement, or order under section 5 or 6;~~

~~"(ii) the contribution of imported articles to the potential risk presented by exposure to the chemical substance or mixture subject to rule under section 5 or 6;~~

~~"(iii) the impact on commerce and potential for the certification to impede or disrupt import of articles;~~

~~"(iv) the frequency or duration of the certification requirement; and~~

~~"(v) specification of the concentration of a chemical substance in an article that would subject the article to the certification requirement.~~

~~"(3) Reasonable inquiry.—~~

~~"(A) In general.—For purposes of a certification under paragraph (1), reasonable inquiry shall include good faith reliance by an importer on—~~

~~"(i) a safety data sheet or similar declaration provided by a supplier that documents the specific identity of the chemical substance or the specific identities of all chemical substances in a mixture; or~~

~~"(ii) for chemical substances or mixtures claimed by the supplier as confidential, or not otherwise disclosed by the supplier, a certification by the supplier that the imported chemical substance or mixture satisfies the applicable certification requirements under paragraph (1).~~

~~"(B) Articles.—For purposes of a certification under paragraph (2), reasonable inquiry shall include good faith reliance by an importer on a certification by the supplier that the imported article satisfies the applicable certification requirements in a rule promulgated pursuant to paragraph (2).~~

~~"(4) Information regarding identity.—For purposes of this subsection, the Administrator shall provide publicly accessible information regarding the identity of a chemical substance or mixture subject to rule under this Act that would be readily understood in import transactions.~~

~~"(c) Notice.—A person offering a chemical substance for entry into the customs territory of the United States shall notify the Secretary of Homeland Security if—~~

~~"(1) the chemical substance or chemical substance in a mixture is a high-priority substance;~~

~~"(2) the chemical substance or chemical substance in a mixture is 1 for which the United States is obligated to provide export notification by treaty; or~~

~~"(3) the chemical substance or chemical substance in a mixture—~~

~~"(A) is the subject of a safety assessment and safety determination conducted pursuant to section 6; and~~

~~"(B) has been found not to meet the safety standard.~~

~~"(d) Rules.—~~

~~"(1) In general.—The Secretary of Homeland Security, after consultation with the Administrator, shall promulgate rules to carry out this section.~~

~~"(2) Application.—The rules under paragraph (1) may modify~~

~~the application of any requirement of this section, as appropriate for the efficient and effective implementation of this Act.".~~

~~SEC. 15~~. CONFIDENTIAL INFORMATION.

Section 14 of the Toxic Substances Control Act (15 U.S.C. 2613) is amended to read as follows:

"SEC. 14. CONFIDENTIAL INFORMATION.

"(a) In General.—Except as otherwise provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, under subsection (b)(4) of that section—

"(1) that is reported to, or otherwise obtained by, the Administrator under this Act; and

"(2) for which the requirements of subsection (d) are met.

"(b) Information Generally Protected From Disclosure.—The following information specific to, and submitted by, a manufacturer, processor, or distributor that meets the requirements of subsections (a) and (d) shall be presumed to be protected from disclosure, subject to the condition that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law:

"(1) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

"(2) Marketing and sales information.

"(3) Information identifying a supplier or customer.

"(4) Details of the full composition of a mixture and the respective percentages of constituents.

"(5) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or product.

"(6) Specific production or import volumes of the manufacturer and specific aggregated volumes across manufacturers, if the Administrator determines that disclosure of the specific aggregated volumes would reveal confidential information.

"(7) Except as otherwise provided in this section, the specific identity of a chemical substance prior to the date on which the chemical substance is first offered for commercial distribution, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify a specific chemical substance, if—

"(A) the specific identity was claimed as confidential information at the time it was submitted in a notice under section 5; and

"(B) the claim—

"(i) is not subject to an exception under subsection (e); or

"(ii) has not subsequently been withdrawn or found by the Administrator not to

warrant protection as confidential information under subsection (f)(2) or (g).

"(c) Information Not Protected From Disclosure.—Notwithstanding subsections (a) and (b), the following information shall not be protected from disclosure:

"(1) INFORMATION FROM HEALTH AND SAFETY STUDIES.—

"(A) IN GENERAL.—Subject to subparagraph (B), subsection (a) does not prohibit the disclosure of—

"(i) any health and safety study that is submitted under this Act with respect to—

"(I) any chemical substance or mixture that, on the date on which the study is to be disclosed, has been offered for commercial distribution; or

"(II) any chemical substance or mixture for which—

"(aa) testing is required under section 4; or

"(bb) a notification is required under section 5; or

"(ii) any information reported to, or otherwise obtained by, the Administrator from a health and safety study relating to a chemical substance or mixture described in subclause (I) or (II) of clause (i).

"(B) EFFECT OF PARAGRAPH.—Nothing in this paragraph authorizes the release of any information that discloses—

"(i) a process used in the manufacturing or processing of a chemical substance or mixture; or

"(ii) in the case of a mixture, the portion of the mixture comprised by any chemical substance in the mixture.

"(2) CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information that is described in paragraph (1) that is not described in paragraph (1)(B), the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

"(3) OTHER INFORMATION NOT PROTECTED FROM DISCLOSURE.—The following information is not protected from disclosure under this section:

"(A) For information submitted after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution, if the person submitting the information does not meet the requirements of subsection (d).

"(B) A safety assessment developed, or a safety determination made, under section 6.

"(C) Any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges.

"(D) A general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

"(4) MIXED CONFIDENTIAL AND NONCONFIDENTIAL ~~INFORMATION.—ANY~~ **INFORMATION .—Any** information that is otherwise eligible for protection under this section and contained in a submission of information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission that is not eligible for protection against disclosure shall be disclosed.

"(5) BAN OR PHASE-OUT.—If the Administrator promulgates a rule pursuant to section 6(d) that establishes a ban or phase-out of the manufacture, processing, or distribution in commerce of a chemical substance—

"(A) any protection from disclosure provided under this section with respect to information relating to the chemical substance shall no longer apply; and

"(B) the Administrator promptly shall make the information public.

"(d) Requirements for Confidentiality Claims.—

"(1) ASSERTION OF CLAIMS.—

"(A) IN GENERAL.—A person seeking to protect any information submitted under this Act from disclosure (including information described in subsection (b)) shall assert to the Administrator a claim for protection concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title.

"(B) INCLUSION.—An assertion of a claim under subparagraph (A) shall include a statement that the person has—

"(i) taken reasonable measures to protect the confidentiality of the information;

"(ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

"(iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

"(iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

"(C) SPECIFIC CHEMICAL IDENTITY.—In the case of a claim under subparagraph (A) for protection against disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that the generic name shall—

"(i) conform with guidance prescribed by the Administrator under paragraph

(3)(A); and

"(ii) describe the chemical structure of the substance as specifically as practicable while protecting those features of the chemical structure—

"(I) that are considered to be confidential; and

"(II) the disclosure of which would be likely to harm the competitive position of the person.

"(D) PUBLIC INFORMATION.—No person may assert a claim under this section for protection from disclosure of information that is already publicly available.

"(2) ADDITIONAL REQUIREMENTS FOR CONFIDENTIALITY CLAIMS.—Except for information described in paragraphs (1) through (7) of subsection (b), a person asserting a claim to protect information from disclosure under this Act shall substantiate the claim, in accordance with the rules promulgated and guidance issued by the Administrator.

"(3) GUIDANCE.—The Administrator shall develop guidance regarding—

"(A) the determination of structurally descriptive generic names, in the case of claims for the protection against disclosure of specific chemical identity; and

"(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (e).

"(4) CERTIFICATION.—An authorized official of a person described in paragraph (1)(A) shall certify that the information that has been submitted is true and correct.

"(e) Exceptions to Protection From Disclosure.—Information described in subsection (a) shall be disclosed if—

"(1) the information is to be disclosed to an officer or employee of the United States in connection with the official duties of the officer or employee—

"(A) under any law for the protection of health or the environment; or

"(B) for a specific law enforcement purpose;

"(2) the information is to be disclosed to a contractor of the United States and employees of that contractor—

"(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act; and

"(B) subject to such conditions as the Administrator may specify;

"(3) the Administrator determines that disclosure is necessary to protect health or the environment;

"(4) the information is to be disclosed to a State or political subdivision of a State, on written request, for the purpose of development, administration, or enforcement of a law, if—

"(A) 1 or more applicable agreements with the Administrator that conform with the guidance issued under subsection (d)(3)(B) ensure that the recipient will take

appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information; and

"(B) the Administrator notifies the person that submitted the information that the information has been disclosed to the State or political subdivision of a State;

"(5) a health or environmental professional employed by a Federal or State agency or a treating physician or nurse in a nonemergency situation provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

"(A) the statement of need and confidentiality agreement shall conform with the guidance issued under subsection (d)(3)(B);

"(B) the written statement of need shall be a statement that the person has a reasonable basis to suspect that—

"(i) the information is necessary for, or will assist in—

"(I) the diagnosis or treatment of 1 or more individuals; or

"(II) responding to an environmental release or exposure; and

"(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance concerned, or an environmental release or exposure has occurred; and

"(C) the confidentiality agreement shall provide that the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person submitting the information to the Administrator, except that nothing in this Act prohibits the disclosure of any such information through discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law;

"(6) in the event of an emergency, a treating physician, nurse, agent of a poison control center, public health or environmental official of a State or political subdivision of a State, or first responder (including any individual duly authorized by a Federal agency, State, or political subdivision of a State who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) requests the information, subject to the conditions that—

"(A) the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall have a reasonable basis to suspect that—

"(i) a medical or public health or environmental emergency exists;

"(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

"(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance concerned, or a serious environmental release of or

exposure to the chemical substance concerned has occurred;

"(B) if requested by the person submitting the information to the Administrator, the treating physician, nurse, agent, public health or environmental official of a State or a political subdivision of a State, or first responder shall, as described in paragraph (5)—

"(i) provide a written statement of need; and

"(ii) agree to sign a confidentiality agreement; and

"(C) the written confidentiality agreement or statement of need shall be submitted as soon as practicable, but not necessarily before the information is disclosed;

"(7) the Administrator determines that disclosure is relevant in a proceeding under this Act, subject to the condition that the disclosure shall be made in such a manner as to preserve confidentiality to the maximum extent practicable without impairing the proceeding;

"(8) the information is to be disclosed, on written request of any duly authorized congressional committee, to that committee; or

"(9) the information is required to be disclosed or otherwise made public under any other provision of Federal law.

"(f) Duration of Protection From Disclosure.—

"(1) IN GENERAL.—

"(A) INFORMATION PROTECTED FROM DISCLOSURE.—Subject to paragraph (2), the Administrator shall protect from disclosure information that meets the requirements of subsection (d) for a period of 10 years, unless, prior to the expiration of the period—

"(i) an affected person notifies the Administrator that the person is withdrawing the confidentiality claim, in which case the Administrator shall promptly make the information available to the public; or

"(ii) the Administrator otherwise becomes aware that the need for protection from disclosure can no longer be substantiated, in which case the Administrator shall take the actions described in subsection (g)(2).

"(B) EXTENSIONS.—

"(i) IN GENERAL.—Not later than the date that is 60 days before the expiration of the period described in subparagraph (A), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

"(ii) STATEMENT.—

"(I) IN GENERAL.—Not later than the date that is 30 days before the expiration of the period described in subparagraph (A), a person reasserting the relevant claim shall submit to the Administrator a statement substantiating, in accordance with subsection (d)(2), the need to extend the period.

"(II) ACTION BY ADMINISTRATOR.—Not later than the date that is 30 days

after the date of receipt of a statement under subclause (I), the Administrator shall—

"(aa) review the request;

"(bb) make a determination regarding whether the information for which the request is made continues to meet the relevant criteria established under this section; and

"(cc)(AA) grant an extension of not more than 10 years; or

"(BB) deny the claim.

"(C) NO LIMIT ON NUMBER OF EXTENSIONS.—There shall be no limit on the number of extensions granted under subparagraph (B), if the Administrator determines that the relevant statement under subparagraph (B)(ii)(I)—

"(i) establishes the need to extend the period; and

"(ii) meets the requirements established by the Administrator.

"(2) REVIEW AND RESUBSTANTIATION.—

"(A) DISCRETION OF ADMINISTRATOR.—The Administrator may review, at any time, a claim for protection against disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) after the chemical substance is identified as a high-priority substance under section 4A;

"(ii) for any chemical substance for which the Administrator has made a determination under section 6(c)(1)(C);

"(iii) for any inactive chemical substance identified under section 8(b)(5); or

"(iv) in limited circumstances, if the Administrator determines that disclosure of certain information currently protected from disclosure would assist the Administrator in conducting safety assessments and safety determinations under subsections (b) and (c) of section 6 or promulgating rules pursuant to section 6(d), subject to the condition that the information shall not be disclosed unless the claimant withdraws the claim or the Administrator determines that the information does not meet the requirements of subsection (d).

"(B) REVIEW REQUIRED.—The Administrator shall review a claim for protection from disclosure under subsection (a) for information submitted to the Administrator regarding a chemical substance and require any person that has claimed protection for that information, whether before, on, or after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to withdraw or reassert and substantiate or resubstantiate the claim in accordance with this section—

"(i) as necessary to comply with a request for information received by the

Administrator under section 552 of title 5, United States Code;

"(ii) if information available to the Administrator provides a basis that the requirements of section 552(b)(4) of title 5, United States Code, are no longer met; or

"(iii) for any substance for which the Administrator has made a determination under section 6(c)(1)(B).

"(C) ACTION BY RECIPIENT.—If the Administrator makes a request under subparagraph (A) or (B), the recipient of the request shall—

"(i) reassert and substantiate or resubstantiate the claim; or

"(ii) withdraw the claim.

"(D) PERIOD OF PROTECTION.—Protection from disclosure of information subject to a claim that is reviewed and approved by the Administrator under this paragraph shall be extended for a period of 10 years from the date of approval, subject to any subsequent request by the Administrator under this paragraph.

"(3) UNIQUE IDENTIFIER.—The Administrator shall—

"(A)(i) develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, other than a specific chemical identity or structurally descriptive generic term; and

"(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

"(B) annually publish and update a list of chemical substances, referred to by unique identifier, for which claims to protect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

"(C) ensure that any nonconfidential information received by the Administrator with respect to such a chemical substance during the period of protection from disclosure—

"(i) is made public; and

"(ii) identifies the chemical substance using the unique identifier; and

"(D) for each claim for protection of specific chemical identity that has been denied by the Administrator on expiration of the period for appeal under subsection (g)(3), that has expired, or that has been withdrawn by the submitter, provide public access to the specific chemical identity clearly linked to all nonconfidential information received by the Administrator with respect to the chemical substance.

"(g) Duties of Administrator.—

"(1) DETERMINATION.—

"(A) IN GENERAL.—Except as provided in subsection (b), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (d), and not later than 30 days after the receipt of a request for extension of a claim under subsection (f), review and approve, modify, or deny the claim or request.

"(B) DENIAL OR MODIFICATION.—

"(i) IN GENERAL.—Except as provided in subsections (c) and (f), the Administrator shall deny a claim to protect a chemical identity from disclosure only if the person that has submitted the claim fails to meet the requirements of subsections (a) and (d).

"(ii) REASONS FOR DENIAL OR MODIFICATION.—The Administrator shall provide to a person that has submitted a claim described in clause (i) a written statement of the reasons for the denial or modification of the claim.

"(C) SUBSETS.—The Administrator shall—

"(i) except for claims described in subsection (b)(7), review all claims under this section for the protection against disclosure of the specific identity of a chemical substance; and

"(ii) review a representative subset, comprising at least 25 percent, of all other claims for protection against disclosure.

"(D) EFFECT OF FAILURE TO ACT.—The failure of the Administrator to make a decision regarding a claim for protection against disclosure or extension under this section shall not be the basis for denial or elimination of a claim for protection against disclosure.

"(2) NOTIFICATION.—

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (c), (e), and (f), if the Administrator denies or modifies a claim under paragraph (1), the Administrator shall notify, in writing and by certified mail, the person that submitted the claim of the intent of the Administrator to release the information.

"(B) RELEASE OF INFORMATION.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Administrator shall not release information under this subsection until the date that is 30 days after the date on which the person that submitted the request receives notification under subparagraph (A).

"(ii) EXCEPTIONS.—

"(I) IN GENERAL.—For information under paragraph (3) or (8) of subsection (e), the Administrator shall not release that information until the date that is 15 days after the date on which the person that submitted the claim receives a notification, unless the Administrator determines that release of the information is necessary to protect against an imminent and substantial harm to health or the environment, in which case no prior notification shall be necessary.

"(II) NO NOTIFICATION.—For information under paragraph (1), (2), (6), (7), or (9) of subsection (e), no prior notification shall be necessary.

"(3) APPEALS.—

"(A) IN GENERAL.—If a person receives a notification under paragraph (2) and believes disclosure of the information is prohibited under subsection (a), before the

date on which the information is to be released, the person may bring an action to restrain disclosure of the information in—

"(i) the United States district court of the district in which the complainant resides or has the principal place of business; or

"(ii) the United States District Court for the District of Columbia.

"(B) NO DISCLOSURE.—The Administrator shall not disclose any information that is the subject of an appeal under this section before the date on which the applicable court rules on an action under subparagraph (A).

"(4) ADMINISTRATION.—In carrying out this subsection, the Administrator shall use the procedures described in part 2 of title 40, Code of Federal Regulations (or successor regulations).

"(h) Criminal Penalty for Wrongful Disclosure.—

"(1) OFFICERS AND EMPLOYEES OF UNITED STATES.—

"(A) IN GENERAL.—Subject to paragraph (2), a current or former officer or employee of the United States described in subparagraph (B) shall be guilty of a misdemeanor and fined under title 18, United States Code, or imprisoned for not more than 1 year, or both.

"(B) DESCRIPTION.—A current or former officer or employee of the United States referred to in subparagraph (A) is a current or former officer or employee of the United States who—

"(i) by virtue of that employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (a); and

"(ii) knowing that disclosure of that material is prohibited by subsection (a), willfully discloses the material in any manner to any person not entitled to receive that material.

"(2) OTHER LAWS.—Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, making known of, or making available, information reported or otherwise obtained under this Act.

"(3) CONTRACTORS.—For purposes of this subsection, any contractor of the United States that is provided information in accordance with subsection (e)(2), including any employee of that contractor, shall be considered to be an employee of the United States.

"(i) Applicability.—

"(1) IN GENERAL.—Except as otherwise provided in this section, section 8, or any other applicable Federal law, the Administrator shall have no authority—

"(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information submitted to the Administrator under this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act; or

"(B) to impose substantiation or resubstantiation requirements under this Act that

are more extensive than those required under this section.

"(2) PRIOR ACTIONS.—Nothing in this Act prevents the Administrator from reviewing, requiring substantiation or resubstantiation for, or approving, modifying or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

SEC. ~~16~~ 15. PROHIBITED ACTS.

Section 15 of the Toxic Substances Control Act (15 U.S.C. 2614) is amended by striking paragraph (1) and inserting the following:

"(1) fail or refuse to comply with—

"(A) any rule promulgated, consent agreement entered into, or order issued under section 4;

"(B) any requirement under section 5 or 6;

"(C) any rule promulgated, consent agreement entered into, or order issued under section 5 or 6; or

"(D) any requirement of, or any rule promulgated or order issued pursuant to title II;".

SEC. ~~17.~~ 16. PENALTIES.

Section 16 of the Toxic Substances Control Act (15 U.S.C. 2615) is amended—

(1) in subsection (a)(1)—

(A) in the first sentence—

(i) by inserting "this Act or a rule or order promulgated or issued pursuant to this Act, including" after "a provision of"; and

(ii) by striking "$25,000" and inserting "$37,500"; and

(B) in the second sentence, by striking" violation of section 15 or 409" and inserting "violation of this Act"; and

(2) in subsection (b)—

(A) by striking "Any person who" and inserting the following:

"(1) IN GENERAL.—Any person that";

(B) by striking "section 15 or 409" and inserting "this Act";

(C) by striking "$25,000" and inserting "$50,000"; and

(D) by adding at the end the following:

"(2) IMMINENT DANGER OF DEATH OR SERIOUS BODILY INJURY.—

"(A) IN GENERAL.—Any person that knowingly or willfully violates any provision of this Act, and that knows at the time of the violation that the violation places an

individual in imminent danger of death or serious bodily injury, shall be subject on conviction to a fine of not more than $250,000, or imprisonment for not more than 15 years, or both.

"(B) ORGANIZATIONS.—An organization that commits a violation described in subparagraph (A) shall be subject on conviction to a fine of not more than $1,000,000 for each violation.

"(3) KNOWLEDGE OF IMMINENT DANGER OR INJURY.—For purposes of determining whether a defendant knew that the violation placed another individual in imminent danger of death or serious bodily injury—

"(A) the defendant shall be responsible only for actual awareness or actual belief possessed; and

"(B) knowledge possessed by an individual may not be attributed to the defendant.".

SEC. ~~18~~ 17. STATE-FEDERAL RELATIONSHIP.

Section 18 of the Toxic Substances Control Act (15 U.S.C. 2617) is amended by striking subsections (a) and (b) and inserting the following:

"(a) In General.—

"(1) ESTABLISHMENT OR ENFORCEMENT.—Except as provided in subsections (c), (d), (e), (f), and (g), and subject to paragraph (2), no State or political subdivision of a State may establish or continue to enforce any of the following:

"(A) TESTING AND INFORMATION COLLECTION.—A statute or administrative action to require the development of information on a chemical substance or category of substances that is reasonably likely to produce the same information required under section 4, 5, or 6 in—

"(i) a rule promulgated by the Administrator;

"(ii) a testing consent agreement entered into by the Administrator; or

"(iii) an order issued by the Administrator.

"(B) CHEMICAL SUBSTANCES FOUND TO MEET THE SAFETY STANDARD OR RESTRICTED.—A statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

"(i) found to meet the safety standard and consistent with the scope of the determination made under section 6; or

"(ii) found not to meet the safety standard, after the effective date of the rule issued under section 6(d) for the substance, consistent with the scope of the determination made by the Administrator.

"(C) SIGNIFICANT NEW USE.—A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(2) EFFECTIVE DATE OF PREEMPTION.—Under this subsection, Federal preemption of

State statutes and administrative actions applicable to specific substances shall not occur until the effective date of the applicable action described in paragraph (1) taken by the Administrator.

"(b) New Statutes or Administrative Actions Creating Prohibitions or Other Restrictions.—Except as provided in subsections (c), (d), and (e), no State or political subdivision of a State may establish (after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) a statute or administrative action prohibiting or restricting the manufacture, processing, distribution in commerce or use of a chemical substance that is a high-priority substance designated under section 4A, as of the date on which the Administrator commences a safety assessment under section 6.

"(c) Scope of Preemption.—Federal preemption under subsections (a) and (b) of State statutes and administrative actions applicable to specific substances shall apply only to—

"(1) the chemical substances or category of substances subject to a rule, order, or consent agreement under section 4;

"(2) the uses or conditions of use of such substances that are identified by the Administrator as subject to review in a safety assessment and included in the scope of the safety determination made by the Administrator for the substance, or of any rule the Administrator promulgates pursuant to section 6(d); or

"(3) the uses of such substances that the Administrator has specified as significant new uses and for which the Administrator has required notification pursuant to a rule promulgated under section 5.

"(d) Exceptions.—

"(1) IN GENERAL.—Subsections (a) and (b) shall not apply to a statute or administrative action of a State or a political subdivision of a State applicable to a specific chemical substance that—

"(A) is adopted **or authorized** under the authority of~~, or authorized to comply with,~~ **other Federal law or adopted to satisfy or obtain authorization or approval under** any other Federal law;

"(B) implements a reporting, monitoring, **disclosure,** or other information ~~collection~~ obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal~~, unless the action taken by the State or political subdivision of a State~~— **except to the extent that the action—**

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii)(I) **addresses the same hazards and exposures, with respect to the same conditions of use, as** ~~is already required by a decision by the Administrator under section 5 or 6;~~

~~"(II) is taken to address a health or environmental concern that applies to the~~

~~uses or conditions of use that~~ are included in the scope of ~~a~~ **the** safety determination pursuant to section 6 ~~or the scope of a significant new use rule promulgated pursuant to section 5~~, but is inconsistent with the action of the Administrator; or

~~"(III)~~**"(II)** would cause a violation of the applicable action by the Administrator under section 5 or 6.

"(2) NO PREEMPTION OF STATE STATUTES AND ADMINISTRATIVE ACTIONS.—Nothing in this Act, nor any amendment made by this Act, nor any rule, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, safety determination, scientific assessment, or any protection for public health or the environment that—

"(A) is adopted **or authorized** under the authority of~~, or authorized to comply with,~~ **any other Federal law or adopted to satisfy or obtain authorization or approval under** any other Federal law;

"(B) implements a reporting, monitoring, **disclosure,** or other information ~~collection~~ obligation for the chemical substance not otherwise required by the Administrator under this Act or required under any other Federal law; or

"(C) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, ~~unless the action taken by the State or political subdivision of a State~~ **except to the extent that the action**—

"(i) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

"(ii)(I) **addresses the same hazards and exposures, with respect to the same conditions of use as** ~~is already required by a decision by the Administrator under section 5 or 6;~~

~~"(II) is taken to address a health or environmental concern that applies to the uses or conditions of use that~~ are included in the scope of ~~a~~ **the** safety determination pursuant to section 6 ~~or the scope of a significant new use rule promulgated pursuant to section 5~~, but is inconsistent with the action of the Administrator; or

~~"(III)~~**"(II)** would cause a violation of the applicable action by the Administrator under section 5 or 6.

"(3) APPLICABILITY TO CERTAIN RULES OR ORDERS.—Notwithstanding subsection (e)—

"(A) nothing in this section shall be construed as modifying the effect under this section, as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, of any rule or order promulgated or issued under this Act prior to that effective date; and

"(B) with respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 6 prior to the effective date of the Frank R.

Lautenberg Chemical Safety for the 21st Century Act with regards to manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance, this section (as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) shall govern the preemptive effect of any rule or order that is promulgated or issued respecting such chemical substance or mixture under section 6 of this Act after that effective date, unless the latter rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under subsection (b) or (c) of section 4A or as an additional priority for safety assessment and safety determination under section 4A(d).

"(e) Preservation of Certain State Law.—

"(1) IN GENERAL.—Nothing in this Act, subject to subsection (g) of this section, shall—

"(A) be construed to preempt or otherwise affect any action taken before January 1, 2015, under the authority of a State law that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance; or

"(B) be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003.

"(2) EFFECT OF SUBSECTION.—This subsection does not affect, modify, or alter the relationship between State and Federal law pursuant to any other Federal law.

"(f) State Waivers.—

"(1) IN GENERAL.—Upon application of a State or political subdivision of a State, the Administrator may—

"(A) by rule, exempt from subsection (a), under such conditions as may be prescribed in the rule, a statute or administrative action of that State or political subdivision of the State that relates to the effects of, or exposure to, a chemical substance under the conditions of use if the Administrator determines that—

"(i) compelling State or local conditions warrant granting the waiver to protect health or the environment;

"(ii) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(iii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

"(iv) based on the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is consistent with sound objective scientific practices, the weight of the evidence, and the best available science; or

"(B) exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical

substance under the conditions of use if the Administrator determines that—

"(i) the State has a compelling local interest that warrants granting the waiver to protect health or the environment;

"(ii) compliance with the proposed requirement of the State will not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

"(iii) compliance with the proposed requirement would not cause a violation of any applicable Federal law, rule, or order; and

"(iv) the proposed requirement is grounded in reasonable scientific concern.

"(2) APPROVAL OF A STATE WAIVER REQUEST.—The Administrator shall grant or deny a waiver application—

"(A) not later than 180 days after the date on which an application under paragraph (1)(A) is submitted; and

"(B) not later than 90 days after the date on which an application under paragraph (1)(B) is submitted.

"(3) NOTICE AND COMMENT.—The application of a State or political subdivision of the State shall be subject to public notice and comment.

"(4) FINAL AGENCY ACTION.—The decision of the Administrator on the application of a State or political subdivision of the State shall be—

"(A) considered to be a final agency action; and

"(B) subject to judicial review.

"(5) DURATION OF WAIVERS.—A waiver granted under paragraph (1)(B) shall remain in effect until the later of—

"(A) such time as the safety assessment and safety determination is completed; and

"(B) the date on which compliance with an applicable rule issued under section 6(d) is required.

"(6) JUDICIAL REVIEW OF WAIVERS.—Not later than 60 days after the date on which the Administrator makes a determination on an application of a State or political subdivision of the State under subparagraph (A) or (B) of paragraph (1), any person may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.

"(7) JUDICIAL REVIEW OF PRIORITIZATION SCREENING DECISION.—Not later than 60 days after the date on which the Administrator makes a decision on a recommendation made under section ~~4A(b)(4)~~ **4A(a)(4)(A)** to designate a chemical substance as a low priority **pursuant to section 4A(b)(4)**, the Governor of a State or a State agency with responsibility for protecting health and the environment that submitted the recommendation ~~under section 4A(a)(4)(A), as applicable,~~ may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.

"(g) Savings.—

"(1) NO PREEMPTION OF COMMON LAW OR STATUTORY CAUSES OF ACTION FOR CIVIL RELIEF OR CRIMINAL CONDUCT.—

"(A) IN GENERAL.—Nothing in this Act, nor any amendment made by this Act, nor any safety standard, rule, requirement, standard of performance, safety determination, or scientific assessment implemented pursuant to this Act, shall be construed to preempt, displace, or supplant any state or Federal common law rights or any state or Federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.

"(B) CLARIFICATION OF NO PREEMPTION.—Notwithstanding any other provision of this Act, nothing in this Act, nor any amendments made by this Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any State law, maritime law, or Federal common law or statutory theory.

"(2) NO EFFECT ON PRIVATE REMEDIES.—

"(A) Nothing in this Act, nor any amendments made by this Act, nor any rules, regulations, requirements, safety assessments, safety determinations, scientific assessments, or orders issued pursuant to this Act shall be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.

"(B) This Act does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this Act or rules, regulations, requirements, standards of performance, safety assessments, scientific assessments, or orders issued pursuant to this Act.".

SEC. ~~19~~ 18. JUDICIAL REVIEW.

Section 19 of the Toxic Substances Control Act (15 U.S.C. 2618) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking "section 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8, or under title II or IV" and inserting "section 4(a), 5(d), 6(c), 6(d), 6(g), or 8, or title II or IV"; and

(ii) in subparagraph (B), by striking "an order issued under subparagraph (A) or (B) of section 6(b)(1)" and inserting "an order issued under this title"; and

(B) in paragraph (2), in the first sentence, by striking "paragraph (1)(A)" and inserting "paragraph (1)"; and

(C) by striking paragraph (3); and

(2) in subsection (c)(1)(B)—

(A) in clause (i)—

(i) by striking "section 4(a), 5(b)(4), 6(a), or 6(e)" and inserting "section 4(a), 5(d), 6(d), or 6(g)"; and

(ii) by striking "evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole;" and inserting "evidence (including any matter) in the rulemaking record, taken as a whole; and"; and

(B) by striking clauses (ii) and (iii) and the matter following clause (iii) and inserting the following:

"(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5, United States Code, to be incorporated in the rule, except as part of the rulemaking record, taken as a whole.".

SEC. ~~20~~ 19. CITIZENS' PETITIONS.

Section 21 of the Toxic Substances Control Act (15 U.S.C. 2620) is amended—

(1) in subsection (a), by striking "an order under section 5(e) or 6(b)(2)" and inserting "an order under section 4 or 5(d)"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking "an order under section 5(e), 6(b)(1)(A), or 6(b)(1)(B)" and inserting "an order under section 4 or 5(d)"; and

(B) in paragraph (4), by striking subparagraph (B) and inserting the following:

"(B) DE NOVO PROCEEDING.—

"(i) IN GENERAL.—In an action under subparagraph (A) to initiate a proceeding to promulgate a rule pursuant to section 4, 5, 6, or 8 or an order issued under section 4 or 5, the petitioner shall be provided an opportunity to have the petition considered by the court in a de novo proceeding.

"(ii) DEMONSTRATION.—

"(I) IN GENERAL.—The court in a de novo proceeding under this subparagraph shall order the Administrator to initiate the action requested by the petitioner if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

"(aa) in the case of a petition to initiate a proceeding for the issuance of a rule or order under section 4, the information available to the Administrator is insufficient for the Administrator to perform an action described in section 4, 4A, 5, or 6(d);

"(bb) in the case of a petition to issue an order under section 5(d), there is a reasonable basis to conclude that the chemical substance is not likely to meet the safety standard;

"(cc) in the case of a petition to initiate a proceeding for the issuance of a rule under section 6(d), there is a reasonable basis to conclude that the chemical substance will not meet the safety standard; or

"(dd) in the case of a petition to initiate a proceeding for the issuance of a rule under section 8, there is a reasonable basis to conclude that the rule is necessary to protect health or the environment or ensure that the chemical substance meets the safety standard.

"(II) DEFERMENT.—The court in a de novo proceeding under this subparagraph may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes, if the court finds that—

"(aa) the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act; and

"(bb) there are insufficient resources available to the Administrator to take the action requested by the petitioner.".

SEC. ~~21~~ 20. EMPLOYMENT EFFECTS.

Section 24(b)(2)(B)(ii) of the Toxic Substances Control Act (15 U.S.C. 2623(b)(2)(B)(ii)) is amended by striking "section 6(c)(3)," and inserting "the applicable requirements of this Act;".

SEC. ~~22.~~ 21. STUDIES.

Section 25 of the Toxic Substances Control Act (15 U.S.C. 2624) is repealed.

SEC. ~~23.~~ 22. ADMINISTRATION.

Section 26 of the Toxic Substances Control Act (15 U.S.C. 2625) is amended—

(1) by striking subsection (b) and inserting the following:

"(b) Fees.—

"(1) IN GENERAL.—The Administrator shall establish, not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, by rule—

"(A) the payment of 1 or more reasonable fees as a condition of submitting a notice or requesting an exemption under section 5; ~~and~~

"(B) the payment of 1 or more reasonable fees by a manufacturer or processor that—

"(i) is required to submit a notice pursuant to the rule promulgated under section 8(b)(4)(A)(i) identifying a chemical substance as active;

"(ii) is required to submit a notice pursuant to section 8(b)(5)(B)(i) changing the status of a chemical substance from inactive to active;

"(iii) is required to report information pursuant to the rules promulgated under section 8(a)(4); and

"(iv) manufactures or processes a chemical substance subject to a safety

assessment and safety determination pursuant to section 6.

"(2) UTILIZATION AND COLLECTION OF FEES.—The Administrator shall—

"(A) utilize the fees collected under paragraph (1) only to defray costs associated with the actions of the Administrator—

"(i) to collect, process, review, provide access to, and protect from disclosure (where appropriate) information on chemical substances under this Act;

"(ii) to review notices and make determinations for chemical substances under paragraphs (1) and (3) of section 5(d) and impose any necessary restrictions under section 5(d)(4);

"(iii) to make prioritization decisions under section 4A;

"(iv) to conduct and complete safety assessments and determinations under section 6; and

"(v) to conduct any necessary rulemaking pursuant to section 6(d);

"(B) insofar as possible, collect the fees described in paragraph (1) in advance of conducting any fee-supported activity;

"(C) deposit the fees in the Fund established by paragraph (4)(A); and

"(D) not collect excess fees or retain a significant amount of unused fees.

"(3) AMOUNT AND ADJUSTMENT OF FEES; REFUNDS.—In setting fees under this section, the Administrator shall—

"(A) take into account the cost to the Administrator of conducting the activities described in paragraph (2);

"(B) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

"(C) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to defray approximately 25 percent of the costs of conducting the activities identified in paragraph (2)(A), not to exceed $18,000,000, not including fees under subparagraph (E) of this paragraph;

"(D) reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

"(E) for substances designated as additional priorities pursuant to section 4A(c), establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the safety assessment and safety determination under section 6;

"(F) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under the Federal Advisory Committee Act (5 U.S.C. App.) or subchapter III of chapter 5 of title 5, United States Code, is applicable with respect to such meetings;

"(G) beginning with the fiscal year that is 3 years after the date of enactment of the

Frank R. Lautenberg Chemical Safety for the 21st Century Act, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives, increase or decrease the fees established under paragraph (1) as necessary—

"(i) to ensure that funds deposited in the Fund are sufficient to conduct the activities identified in paragraph (2)(A) and the full costs of safety assessments and safety determinations pursuant to subparagraph (E); and

"(ii) to account for inflation;

"(H) adjust fees established under paragraph (1) as necessary to vary on account of differing circumstances, including reduced fees or waivers in appropriate circumstances, to reduce the burden on manufacturing or processing, remove barriers to innovation, or where the costs to the Administrator of collecting the fees exceed the fee revenue anticipated to be collected; and

"(I) if a notice submitted under section 5 is refused or subsequently withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

"(4) TSCA IMPLEMENTATION FUND.—

"(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the 'TSCA Implementation Fund' (referred to in this subsection as the 'Fund'), consisting of—

"(i) such amounts as are deposited in the Fund under paragraph (2)(C); and

"(ii) any interest earned on the investment of amounts in the Fund; and

"(iii) any proceeds from the sale or redemption of investments held in the Fund.

"(B) CREDITING AND AVAILABILITY OF FEES.—

"(i) IN GENERAL.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation.

"(ii) REQUIREMENTS.—Fees collected under this section shall not—

"(I) be made available or obligated for any purpose other than to defray the costs of conducting the activities identified in paragraph (2)(A);

"(II) otherwise be available for any purpose other than implementation of this Act; and

"(III) so long as amounts in the Fund remain available, be subject to restrictions on expenditures applicable to the Federal government as a whole.

"(C) UNUSED FUNDS.—Amounts in the Fund not currently needed to carry out this subsection shall be—

"(i) maintained readily available or on deposit;

"(ii) invested in obligations of the United States or guaranteed by the United States; or

"(iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

"(D) MINIMUM AMOUNT OF APPROPRIATIONS.—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2015) of the Office of Pollution Prevention and Toxics of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for covered functions for fiscal year 2015 (excluding the amount of any fees appropriated for the fiscal year).

"(5) AUDITING.—

"(A) FINANCIAL STATEMENTS OF AGENCIES.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of an executive agency.

"(B) COMPONENTS.—The annual audit required under sections 3515(b) and 3521 of that title of the financial statements of activities under this subsection shall include an analysis of—

"(i) the fees collected under paragraph (1) and disbursed;

"(ii) compliance with the deadlines established in section 6 of this Act;

"(iii) the amounts budgeted, appropriated, collected from fees, and disbursed to meet the requirements of sections 4, 4A, 5, 6, 8, and 14, including the allocation of full time equivalent employees to each such section or activity; and

"(iv) the reasonableness of the allocation of the overhead associated with the conduct of the activities described in paragraph (2)(A).

"(C) INSPECTOR GENERAL.—The Inspector General of the Environmental Protection Agency shall—

"(i) conduct the annual audit required under this subsection; and

"(ii) report the findings and recommendations of the audit to the Administrator and to the appropriate committees of Congress.

"(6) TERMINATION.—The authority provided by this section shall terminate at the conclusion of the fiscal year that is 10 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, unless otherwise reauthorized or modified by Congress.";

(2) in subsection (e), by striking "Health, Education, and Welfare" each place it appears and inserting "Health and Human Services"; and

(3) adding at the end the following:

"(h) Prior Actions.—Nothing in this Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this Act before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

SEC. ~~24~~ **23**. DEVELOPMENT AND EVALUATION OF TEST

METHODS AND SUSTAINABLE CHEMISTRY.

Section 27 of the Toxic Substances Control Act (15 U.S.C. 2626) is amended—

(1) in subsection (a), in the first sentence by striking "Health, Education, and Welfare" and inserting "Health and Human Services"; and

(2) by adding at the end the following:

"(c) Sustainable Chemistry Program.—The President shall establish an interagency Sustainable Chemistry Program to promote and coordinate Federal sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities.

"(d) Program Activities.—The activities of the Program shall be designed to—

"(1) provide sustained support for sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training through—

"(A) coordination of sustainable chemistry research, development, demonstration, and technology transfer conducted at Federal laboratories and agencies; and

"(B) to the extent practicable, encouragement of consideration of sustainable chemistry in, as appropriate—

"(i) the conduct of Federal and State science and engineering research and development; and

"(ii) the solicitation and evaluation of applicable proposals for science and engineering research and development;

"(2) examine methods by which the Federal Government can create incentives for consideration and use of sustainable chemistry processes and products, including innovative financing mechanisms;

"(3) expand the education and training of undergraduate and graduate students and professional scientists and engineers, including through partnerships with industry, in sustainable chemistry science and engineering;

"(4) collect and disseminate information on sustainable chemistry research, development, and technology transfer including information on—

"(A) incentives and impediments to development, manufacturing, and commercialization;

"(B) accomplishments;

"(C) best practices; and

"(D) costs and benefits; ~~and~~

"(5) support (including through technical assistance, participation, financial support, or other forms of support) economic, legal, and other appropriate social science research to identify barriers to commercialization and methods to advance commercialization of sustainable chemistry.

"(e) Interagency Working Group.—

"(1) ESTABLISHMENT.—Not later than 180 days after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the President, in consultation with the Office of Science and Technology Policy, shall establish an Interagency Working Group that shall include representatives from the National Science Foundation, the National Institute of Standards and Technology, the Department of Energy, the Environmental Protection Agency, the Department of Agriculture, the Department of Defense, the National Institutes of Health, and any other agency that the President may designate to oversee the planning, management, and coordination of the Program.

"(2) GOVERNANCE.—The Director of the National Science Foundation and the Assistant Administrator for Research and Development of the Environmental Protection Agency, or their designees, shall serve as co-chairs of the Interagency Working Group.

"(3) RESPONSIBILITIES.—In overseeing the planning, management, and coordination of the Program, the Interagency Working Group shall—

"(A) establish goals and priorities for the Program, in consultation with the Advisory Council;

"(B) provide for interagency coordination, including budget coordination, of activities under the Program;

"(C) meet not later than 90 days from its establishment and periodically thereafter; and

"(D) establish and consult with an Advisory Council on a regular basis.

"(4) MEMBERSHIP.—The Advisory Council members shall not be employees of the Federal Government and shall include a diverse representation of knowledgeable individuals from the private sector (including small- and medium-sized enterprises from across the value chain), academia, State and tribal governments, and nongovernmental organizations and others who are in a position to provide expertise.

"(f) Agency Budget Requests.—

"(1) IN GENERAL.—Each Federal agency and department participating in the Program shall, as part of its annual request for appropriations to the Office of Management and Budget, submit a report to the Office of Management and Budget that—

"(A) identifies the activities of the agency or department that contribute directly to the Program; and

"(B) states the portion of the agency or department's request for appropriations that is allocated to those activities.

"(2) ANNUAL BUDGET REQUEST TO CONGRESS.—The President shall include in the annual budget request to Congress a statement of the portion of the annual budget request for each agency or department that will be allocated to activities undertaken pursuant to the Program.

"(g) Report to Congress.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Interagency Working Group shall

submit a report to the Committee on Science, Space, and Technology and Committee on Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works and the Committee on Commerce, Science, and Transportation of the Senate that shall include—

"(A) a summary of federally funded sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities;

"(B) a summary of the financial resources allocated to sustainable chemistry initiatives;

"(C) an analysis of the progress made toward achieving the goals and priorities of this Act, and recommendations for future program activities;

"(D) an assessment of the benefits of expanding existing, federally-supported regional innovation and manufacturing hubs to include sustainable chemistry and the value of directing the creation of 1 or more dedicated sustainable chemistry centers of excellence or hubs; and

"(E) an evaluation of steps taken and future strategies to avoid duplication of efforts, streamline interagency coordination, facilitate information sharing, and spread best practices between participating agencies in the Program.

"(2) SUBMISSION TO GAO.—The Interagency Working Group shall also submit the report described in paragraph (1) to the Government Accountability Office for consideration in future Congressional inquiries.".

SEC. ~~25~~ 24. STATE PROGRAMS.

Section 28 of the Toxic Substances Control Act (15 U.S.C. 2627) is amended—

(1) in subsection (b)(1)—

(A) in subparagraphs (A) through (D), by striking the comma at the end of each subparagraph and inserting a semicolon; and

(B) in subparagraph (E), by striking ", and" and inserting "; and"; and

(2) by striking subsections (c) and (d).

SEC. ~~26~~ 25. AUTHORIZATION OF APPROPRIATIONS.

Section 29 of the Toxic Substances Control Act (15 U.S.C. 2628) is repealed.

SEC. ~~27~~ 26. ANNUAL REPORT.

Section 30 of the Toxic Substances Control Act (15 U.S.C. 2629) is amended by striking paragraph (2) and inserting the following:

"(2)(A) the number of notices received during each year under section 5; and

"(B) the number of the notices described in subparagraph (A) for chemical substances subject to a rule, testing consent agreement, or order under section 4;".

SEC. ~~28~~ 27. EFFECTIVE DATE.

Section 31 of the Toxic Substances Control Act (15 U.S.C. 2601 note; Public Law 94–469) is amended—

(1) by striking "Except as provided in section 4(f), this" and inserting the following:

"(a) In General.—This"; and

(2) by adding at the end the following:

"(b) Retroactive Applicability.—Nothing in this Act shall be interpreted to apply retroactively to any State, Federal, or maritime legal action commenced prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.".

AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—114th Cong., 1st Sess.

S. 697

To amend the Toxic Substances Control Act to reauthorize and modernize that Act, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act".

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(c) of the Toxic Substances Control Act (15 U.S.C. 2601(c)) is amended—

(1) by striking "It is the intent" and inserting the following:

"(1) ADMINISTRATION.—It is the intent";

(2) in paragraph (1) (as so redesignated), by inserting ", as provided under this Act" before the period at the end; and

(3) by adding at the following:

"(2) REFORM.—It is the intent of Congress that reform of this Act in accordance with the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act—

"(A) shall be administered in a manner that—

"(i) protects the health of children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemical substances and mixtures; and

"(ii) ensures that appropriate information on chemical substances and mixtures is available to public health officials and first responders in the event of an emergency; and

"(B) shall not displace or supplant common law rights of action or remedies for civil relief.".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

(1) by redesignating paragraphs (4), (5), (6), (7), (8), (9), (10), (11), (12), (13), and (14) as paragraphs (5), (6), (7), (8), (9), (10), (12), (13), (17), (18), and (19), respectively;

(2) by inserting after paragraph (3) the following:

"(4) CONDITIONS OF USE.—The term 'conditions of use' means the intended, known, or reasonably foreseeable circumstances the Administrator determines a chemical substance is manufactured, processed, distributed in commerce, used, or disposed of.";

(3) by inserting after paragraph (10) (as so redesignated) the following:

"(11) POTENTIALLY EXPOSED OR SUSCEPTIBLE POPULATION.—The term 'potentially exposed or susceptible population' means 1 or more groups—

"(A) of individuals within the general population who may be—

"(i) differentially exposed to chemical substances under the conditions of use; or

"(ii) susceptible to greater adverse health consequences from chemical exposures than the general population; and

"(B) that when identified by the Administrator may include such groups as infants, children, pregnant women, workers, and the elderly."; and

(4) by inserting after paragraph (13) (as so redesignated) the following:

"(14) SAFETY ASSESSMENT.—The term 'safety assessment' means an assessment of the risk posed by a chemical substance under the conditions of use, integrating hazard, use, and exposure information regarding the chemical substance.

"(15) SAFETY DETERMINATION.—The term 'safety determination' means a determination by the Administrator as to whether a chemical substance meets the safety standard under the conditions of use.

"(16) SAFETY STANDARD.—The term 'safety standard' means a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of harm to health or the environment will result from exposure to a chem-

ical substance under the conditions of use, including no unreasonable risk of harm to—

"(A) the general population; or

"(B) any potentially exposed or susceptible population that the Administrator has identified as relevant to the safety assessment and safety determination for a chemical substance.".

SEC. 4. POLICIES, PROCEDURES, AND GUIDANCE.

The Toxic Substances Control Act is amended by inserting after section 3 (15 U.S.C. 2602) the following:

"SEC. 3A. POLICIES, PROCEDURES, AND GUIDANCE.

"(a) DEFINITION OF GUIDANCE.—In this section, the term 'guidance' includes any significant written guidance of general applicability prepared by the Administrator.

"(b) DEADLINE.—Not later than 2 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop, after providing public notice and an opportunity for comment, any policies, procedures, and guidance the Administrator determines to be necessary to carry out sections 4, 4A, 5, and 6, including the policies, procedures, and guidance required by this section.

"(c) USE OF SCIENCE.—

"(1) IN GENERAL.—The Administrator shall establish policies, procedures, and guidance on the use

of science in making decisions under sections 4, 4A, 5, and 6.

"(2) GOAL.—A goal of the policies and procedures described in paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) REQUIREMENTS.—The policies, procedures, and guidance issued under this section shall describe the manner in which the Administrator shall ensure that —

"(A) decisions made by the Administrator—

"(i) are based on information, procedures, measures, methods, and models employed in a manner consistent with the best available science;

"(ii) take into account the extent to which—

"(I) assumptions and methods are clearly and completely described and documented;

"(II) variability and uncertainty are evaluated and characterized; and

"(III) the information has been subject to independent verification and peer review; and

"(iii) are based on the weight of the scientific evidence, by which the Administrator considers all information in a systematic and integrative framework to consider the relevance of different information;

"(B) to the extent practicable and if appropriate, the use of peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices will be encouraged;

"(C) a clear description of each individual and entity that funded the generation or assessment of information, and the degree of control those individuals and entities had over the generation, assessment, and dissemination of information (including control over the design of the work and the publication of information) is made available; and

"(D) if appropriate, the recommendations in reports of the National Academy of Sciences that provide advice regarding assessing the hazards, exposures, and risks of chemical substances are considered.

"(d) EXISTING EPA POLICIES, PROCEDURES, AND GUIDANCE.—The policies, procedures, and guidance described in subsection (b) shall incorporate, as appropriate, existing relevant hazard, exposure, and risk assessment guidelines and methodologies, data evaluation and quality criteria, testing methodologies, and other relevant guidelines and policies of the Environmental Protection Agency.

"(e) REVIEW.—Not later than 5 years after the date of enactment of this section, and not less frequently than once every 5 years thereafter, the Administrator shall—

"(1) review the adequacy of any policies, procedures, and guidance developed under this section, including animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this Act; and

"(2) after providing public notice and an opportunity for comment, revise the policies, procedures, and guidance if necessary to reflect new scientific developments or understandings.

"(f) SOURCES OF INFORMATION.—In making any decision with respect to a chemical substance under section 4, 4A, 5, or 6, the Administrator shall take into consideration information relating to the hazards and exposures of a chemical substance under the conditions of use that

is reasonably available to the Administrator, including information that is—

"(1) submitted to the Administrator pursuant to any rule, consent agreement, order, or other requirement of this Act, or on a voluntary basis, including pursuant to any request made under this Act, by—

"(A) manufacturers or processors of a substance;

"(B) the public;

"(C) other Federal departments or agencies; or

"(D) the Governor of a State or a State agency with responsibility for protecting health or the environment;

"(2) submitted to a governmental entity in any jurisdiction pursuant to a governmental requirement relating to the protection of health or the environment; or

"(3) identified through an active search by the Administrator of information sources that are publicly available or otherwise accessible by the Administrator.

"(g) TESTING OF CHEMICAL SUBSTANCES AND MIXTURES.—

"(1) IN GENERAL.—The Administrator shall establish policies and procedures for the testing of chemical substances or mixtures under section 4.

"(2) GOAL.—A goal of the policies and procedures established under paragraph (1) shall be to make the basis of decisions clear to the public.

"(3) CONTENTS.—The policies and procedures established under paragraph (1) shall—

"(A) address how and when the exposure level or exposure potential of a chemical substance would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential;

"(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this Act, including information relating to potentially exposed or susceptible populations;

"(C) require the Administrator to consult with the Director of the National Institute for Occupational Safety and Health prior to prescribing epidemiologic studies of employees; and

"(D) prior to adopting a requirement for testing using vertebrate animals, require the Administrator to take into consideration, as appropriate and to the extent practicable, reasonably available—

"(i) toxicity information;

"(ii) computational toxicology and bioinformatics;

"(iii) high-throughput screening methods and the prediction models of those methods; and

"(iv) scientifically reliable and relevant alternatives to tests on animals that would provide equivalent information.

"(h) SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(1) SCHEDULE.—

"(A) IN GENERAL.—The Administrator shall inform the public regarding the schedule for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance pursuant to section 4A.

"(B) DIFFERING TIMES.—The Administrator may allot different times for different

chemical substances in the schedules under this paragraph, subject to the condition that all schedules shall comply with the deadlines established under section 6.

"(C) ANNUAL PLAN.—At the beginning of each calendar year, the Administrator shall identify the substances subject to safety assessments and safety determinations to be completed that year.

"(2) POLICIES AND PROCEDURES FOR SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.—

"(A) IN GENERAL.—The Administrator shall establish, by rule, policies and procedures regarding the manner in which the Administrator shall carry out section 6.

"(B) GOAL.—A goal of the policies and procedures under this paragraph shall be to make the basis of decisions of the Administrator clear to the public.

"(C) MINIMUM REQUIREMENTS.—At a minimum, the policies and procedures under this paragraph shall—

"(i) describe—

"(I) the manner in which the Administrator will identify informational

needs and seek that information from the public;

"(II) the information (including draft safety assessments) that may be submitted by interested individuals or entities, including States; and

"(III) the criteria by which that information will be evaluated;

"(ii) require the Administrator—

"(I)(aa) to define the scope of the safety assessment and safety determination to be conducted under section 6, including the hazards, exposures, conditions of use, and potentially exposed and susceptible populations that the Administrator expects to consider in a safety assessment;

"(bb) to explain the basis for the scope of the safety assessment and safety determination; and

"(cc) to accept comments regarding the scope of the safety assessment and safety determination; and

"(II)(aa) to identify the items described in subclause (I) that the Ad-

ministrator has considered in the final safety assessment; and

"(bb) to explain the basis for the consideration of those items;

"(iii) describe the manner in which aggregate exposures, or significant subsets of exposures, to a chemical substance under the conditions of use will be considered, and explain the basis for that consideration in the final safety assessment;

"(iv) require that each safety assessment and safety determination shall include—

"(I) a description of the weight of the scientific evidence of risk; and

"(II) a summary of the information regarding the impact on health and the environment of the chemical substance that was used to make the assessment or determination, including, as available, mechanistic, animal toxicity, and epidemiology studies;

"(v) establish a timely and transparent process for evaluating whether new information submitted or obtained after

the date of a final safety assessment or safety determination warrants reconsideration of the safety assessment or safety determination; and

"(vi) when relevant information is provided or otherwise made available to the Administrator, shall consider the extent of Federal regulation under other Federal laws.

"(D) GUIDANCE.—

"(i) IN GENERAL.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop guidance to assist interested persons in developing their own draft safety assessments and other information for submission to the Administrator, which may be considered at the discretion of the Administrator.

"(ii) REQUIREMENT.—The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing a draft assess-

ment for consideration by the Administrator.

"(i) PUBLICLY AVAILABLE INFORMATION.—Subject to section 14, the Administrator shall—

"(1) make publicly available a nontechnical summary, and the final version, of each safety assessment and safety determination;

"(2) provide public notice and an opportunity for comment on each proposed safety assessment and safety determination; and

"(3) make public in a final safety assessment and safety determination—

"(A) the list of studies considered by the Administrator in carrying out the safety assessment or safety determination; and

"(B) the list of policies, procedures, and guidance that were followed in carrying out the safety assessment or safety determination.

"(j) CONSULTATION WITH SCIENCE ADVISORY COMMITTEE ON CHEMICALS.—

"(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish an advisory committee, to be known as the 'Science Advisory Committee on

Chemicals' (referred to in this subsection as the 'Committee').

"(2) PURPOSE.—The purpose of the Committee shall be to provide independent advice and expert consultation, on the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title.

"(3) COMPOSITION.—The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including, at a minimum, representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible populations.

"(4) SCHEDULE.—The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

"(5) RELATIONSHIP TO OTHER LAW.—All proceedings and meetings of the Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).".

SEC. 5. TESTING OF CHEMICAL SUBSTANCES OR MIXTURES.

(a) IN GENERAL.—Section 4 of the Toxic Substances Control Act (15 U.S.C. 2603) is amended—

(1) by striking subsections (a), (b), (c), (d), and (g);

(2) by redesignating subsections (e) and (f) as subsections (f) and (g), respectively;

(3) in subsection (f) (as so redesignated)—

(A) by striking "rule" each place it appears and inserting "rule, testing consent agreement, or order";

(B) by striking "under subsection (a)" each place it appears and inserting "under this subsection"; and

(C) in paragraph (1)(B), in the last sentence, by striking "rulemaking";

(4) in subsection (g) (as so redesignated)—

(A) in the first sentence, by striking "from cancer, gene mutations, or birth defects"; and

(B) by striking the last sentence; and

(5) by inserting before subsection (f) (as so redesignated) the following:

"(a) DEVELOPMENT OF NEW INFORMATION ON CHEMICAL SUBSTANCES AND MIXTURES.—

"(1) IN GENERAL.—The Administrator may require the development of new information relating to

a chemical substance or mixture in accordance with this section if the Administrator determines that the information is necessary—

"(A) to review a notice under section 5(d) or to perform a safety assessment or safety determination under section 6;

"(B) to implement a requirement imposed in a consent agreement or order issued under section 5(d)(4) or under a rule promulgated under section 6(d)(3);

"(C) pursuant to section 12(a)(4); or

"(D) at the request of the implementing authority under another Federal law, to meet the regulatory testing needs of that authority.

"(2) LIMITED TESTING FOR PRIORITIZATION PURPOSES.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), the Administrator may require the development of new information for the purposes of section 4A.

"(B) PROHIBITION.—Testing required under subparagraph (A) shall not be required for the purpose of establishing or implementing a minimum information requirement.

"(C) LIMITATION.—The Administrator may require the development of new information pursuant to subparagraph (A) only if the Administrator determines that additional information is necessary to establish the priority of a chemical substance.

"(3) FORM.—Subject to section 3A(h), the Administrator may require the development of information described in paragraph (1) or (2) by—

"(A) promulgating a rule;

"(B) entering into a testing consent agreement; or

"(C) issuing an order.

"(4) CONTENTS.—

"(A) IN GENERAL.—A rule, testing consent agreement, or order issued under this subsection shall include—

"(i) identification of the chemical substance or mixture for which testing is required;

"(ii) identification of the persons required to conduct the testing;

"(iii) test protocols and methodologies for the development of test data and information for the chemical substance or mix-

ture, including specific reference to reliable nonanimal test procedures; and

"(iv) specification of the period within which individuals and entities required to conduct the testing shall submit to the Administrator the information developed in accordance with the procedures described in clause (iii).

"(B) CONSIDERATIONS.—In determining the procedures and period to be required under subparagraph (A), the Administrator shall take into consideration—

"(i) the relative costs of the various test protocols and methodologies that may be required; and

"(ii) the reasonably foreseeable availability of facilities and personnel required to perform the testing.

"(b) STATEMENT OF NEED.—

"(1) IN GENERAL.—In promulgating a rule, entering into a testing consent agreement, or issuing an order for the development of additional information (including information on exposure or exposure potential) pursuant to this section, the Administrator shall—

"(A) identify the need intended to be met by the rule, agreement, or order;

"(B) explain why information reasonably available to the Administrator at that time is inadequate to meet that need, including a reference, as appropriate, to the information identified in paragraph (2)(B); and

"(C) explain the basis for any decision that requires the use of vertebrate animals.

"(2) EXPLANATION IN CASE OF ORDER.—

"(A) IN GENERAL.—If the Administrator issues an order under this section, the Administrator shall issue a statement providing a justification for why issuance of an order is warranted instead of promulgating a rule or entering into a testing consent agreement.

"(B) CONTENTS.—A statement described in subparagraph (A) shall contain a description of—

"(i) information that is readily accessible to the Administrator, including information submitted under any other provision of law;

"(ii) the extent to which the Administrator has obtained or attempted to obtain

the information through voluntary submissions; and

"(iii) any information relied on in safety assessments for other chemical substances relevant to the chemical substances that would be the subject of the order.

"(c) REDUCTION OF TESTING ON VERTEBRATES.—

"(1) IN GENERAL.—The Administrator shall minimize, to the extent practicable, the use of vertebrate animals in testing of chemical substances or mixtures, by—

"(A) encouraging and facilitating—

"(i) the use of integrated and tiered testing and assessment strategies;

"(ii) the use of best available science in existence on the date on which the test is conducted;

"(iii) the use of test methods that eliminate or reduce the use of animals while providing information of high scientific quality;

"(iv) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide reli-

able and useful information on other chemical substances in the category;

"(v) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests; and

"(vi) the submission of information from—

"(I) animal-based studies; and

"(II) emerging methods and models; and

"(B) funding research and validation studies to reduce, refine, and replace the use of animal tests in accordance with this subsection.

"(2) IMPLEMENTATION OF ALTERNATIVE TESTING METHODS.—To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the Administrator shall—

"(A) after providing an opportunity for public comment, develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information under this title that can reduce, refine, or replace the use of vertebrate animals, including toxicity pathway-based risk

assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening;

"(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is reflected in the development of requirements for testing under this section;

"(C) beginning on the date that is 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing this subsection and goals for future alternative test methods implementation; and

"(D) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and testing strategies that reduce, refine, or replace the use of vertebrate animals in any testing under this title.

"(3) CRITERIA FOR ADAPTING OR WAIVING ANIMAL TESTING REQUIREMENTS.—On request from a manufacturer or processor that is required to conduct testing of a chemical substance or mixture on

vertebrate animals under this section, the Administrator may adapt or waive the requirement, if the Administrator determines that—

"(A) there is sufficient evidence from several independent sources of information to support a conclusion that a chemical substance or mixture has, or does not have, a particular property if the information from each individual source alone is insufficient to support the conclusion;

"(B) as a result of 1 or more physical or chemical properties of the chemical substance or mixture or other toxicokinetic considerations—

"(i) the substance cannot be absorbed; or

"(ii) testing for a specific endpoint is technically not practicable to conduct; or

"(C) a chemical substance or mixture cannot be tested in vertebrate animals at concentrations that do not result in significant pain or distress, because of physical or chemical properties of the chemical substance or mixture, such as a potential to cause severe corrosion or severe irritation to the tissues of the animal.

"(d) TESTING REQUIREMENTS.—

"(1) IN GENERAL.—The Administrator may require the development of information by—

"(A) manufacturers and processors of the chemical substance or mixture; and

"(B) subject to paragraph (3), persons that begin to manufacture or process the chemical substance or mixture—

"(i) after the effective date of the rule, testing consent agreement, or order; but

"(ii) before the period ending on the later of—

"(I) 5 years after the date referred to in clause (i); or

"(II) the last day of the period that begins on the date referred to in clause (i) and that is equal to the period that the Administrator determines was necessary to develop the information.

"(2) DESIGNATION.—The Administrator may permit 2 or more persons identified in subparagraph (A) or (B) of paragraph (1) to designate 1 of the persons or a qualified third party—

"(A) to develop the information; and

"(B) to submit the information on behalf of the persons making the designation.

"(3) EXEMPTIONS.—

"(A) IN GENERAL.—A person otherwise subject to a rule, testing consent agreement, or order under this section may submit to the Administrator an application for an exemption on the basis that the information is being developed by a person designated under paragraph (2).

"(B) FAIR AND EQUITABLE REIMBURSEMENT TO DESIGNEE.—

"(i) IN GENERAL.—If the Administrator accepts an application submitted under subparagraph (A), the Administrator shall direct the applicant to provide to the person designated under paragraph (2) fair and equitable reimbursement, as agreed to between the applicant and the designee.

"(ii) ARBITRATION.—If the applicant and a person designated under paragraph (2) cannot reach agreement on the amount

of fair and equitable reimbursement, the amount shall be determined by arbitration.

"(C) TERMINATION.—If, after granting an exemption under this paragraph, the Administrator determines that a person covered by the exemption has failed to comply with the rule, testing consent agreement, or order, the Administrator shall—

"(i) by order, terminate the exemption; and

"(ii) notify in writing each person that received an exemption of the requirements with respect to which the exemption was granted.

"(4) TIERED TESTING.—

"(A) IN GENERAL.—Except as provided in subparagraph (D), the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary.

"(B) SCREENING-LEVEL TESTS.—

"(i) IN GENERAL.—The screening-level tests required for a chemical sub-

stance or mixture may include tests for hazard (which may include in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of exposure or exposure potential, as appropriate.

"(ii) USE.—Screening-level tests shall be used—

"(I) to screen chemical substances or mixtures for potential adverse effects; and

"(II) to inform a decision of the Administrator regarding whether more complex or targeted additional testing is necessary.

"(C) ADDITIONAL TESTING.—If the Administrator determines under subparagraph (B) that additional testing is necessary to provide more definitive information for safety assessments or safety determinations, the Administrator may require more advanced tests for potential health or environmental effects or exposure potential.

"(D) ADVANCED TESTING WITHOUT SCREENING.—The Administrator may require

more advanced testing without conducting screening-level testing when other information available to the Administrator justifies the advanced testing, pursuant to guidance developed by the Administrator under this section.

"(e) TRANSPARENCY.—Subject to section 14, the Administrator shall make available to the public all testing consent agreements and orders and all information submitted under this section.".

(b) CONFORMING AMENDMENT.—Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)) is amended in the third sentence by striking "section 4(e)" and inserting "section 4(f)".

SEC. 6. PRIORITIZATION SCREENING.

The Toxic Substances Control Act is amended by inserting after section 4 (15 U.S.C. 2603) the following:

"SEC. 4A. PRIORITIZATION SCREENING.

"(a) ESTABLISHMENT AND LIST OF SUBSTANCES.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Administrator shall establish, by rule, a risk-based screening process and explicit criteria for identifying existing chemical substances that are—

"(A) a high priority for a safety assessment and safety determination under section 6 (referred to in this Act as 'high-priority substances'); and

"(B) a low priority for a safety assessment and safety determination (referred to in this Act as 'low-priority substances').

"(2) INITIAL LIST OF HIGH- AND LOW-PRIORITY SUBSTANCES.—

"(A) IN GENERAL.—Before the date of promulgation of the rule under paragraph (1) and not later than 180 days after the date of enactment of this section, the Administrator—

"(i) shall take into consideration and publish an initial list of high-priority substances and low-priority substances; and

"(ii) pursuant to section 6(b), may initiate or continue safety assessments and safety determinations for those high-priority substances.

"(B) REQUIREMENTS.—

"(i) IN GENERAL.—The initial list of chemical substances shall contain at least 10 high-priority substances, at least 5 of which are drawn from the list of chemical

substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, and at least 10 low-priority substances.

"(ii) SUBSEQUENTLY IDENTIFIED SUBSTANCES.—Insofar as possible, at least 50 percent of all substances subsequently identified by the Administrator as high-priority substances shall be drawn from the list of chemical substances identified by the Administrator in the October 2014 TSCA Work Plan and subsequent updates, until all Work Plan chemicals have been designated under this subsection.

"(iii) PERSISTENCE AND BIOACCUMULATION.—In developing the initial list and in identifying additional high-priority substances, the Administrator shall give preference to chemical substances scored as high for persistence and bioaccumulation in the October 2014 TSCA Work Plan and subsequent updates.

"(C) ADDITIONAL CHEMICAL REVIEWS.—The Administrator shall, as soon as practicable—

"(i) 3 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 20 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 20 low-priority substances have been designated; and

"(ii) 5 years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, add additional high-priority substances sufficient to ensure that at least a total of 25 high-priority substances have undergone or are undergoing the process established in section 6(a), and additional low-priority substances sufficient to ensure that at least a total of 25 low-priority substances have been designated.

"(3) IMPLEMENTATION.—

"(A) CONSIDERATION OF ACTIVE AND INACTIVE SUBSTANCES.—

"(i) ACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator shall take into consideration active substances, as determined under section 8, which may include chemical substances on the interim list of active substances established under that section.

"(ii) INACTIVE SUBSTANCES.—In carrying out paragraph (1), the Administrator may take into consideration inactive substances, as determined under section 8, that the Administrator determines—

"(I)(aa) have not been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) have the potential for high hazard and widespread exposure; or

"(II)(aa) have been subject to a regulatory or other enforceable action by the Administrator to ban or phase out the substances; and

"(bb) with respect to which there exists the potential for residual high hazards or widespread exposures not

otherwise addressed by the regulatory or other action.

"(iii) REPOPULATION.—

"(I) IN GENERAL.—On the completion of a safety determination under section 6 for a chemical substance, the Administrator shall remove the chemical substance from the list of high-priority substances established under this subsection.

"(II) ADDITIONS.—The Administrator shall add at least 1 chemical substance to the list of high-priority substances for each chemical substance removed from the list of high-priority substances established under this subsection, until a safety assessment and safety determination is completed for all high-priority substances.

"(III) LOW-PRIORITY SUBSTANCES.—If a low-priority substance is subsequently designated as a high-priority substance, the Administrator shall remove that substance from the list of low-priority substances.

"(B) TIMELY COMPLETION OF PRIORITIZATION SCREENING PROCESS.—

"(i) IN GENERAL.—The Administrator shall—

"(I) not later than 180 days after the effective date of the final rule under paragraph (1), begin the prioritization screening process; and

"(II) make every effort to complete the designation of all active substances as high-priority substances or low-priority substances in a timely manner.

"(ii) DECISIONS ON SUBSTANCES SUBJECT TO TESTING FOR PRIORITIZATION PURPOSES.—Not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, testing consent agreement, or order issued under section 4(a)(2), the Administrator shall designate the chemical substance as a high-priority substance or low-priority substance.

"(iii) CONSIDERATION.—

"(I) IN GENERAL.—The Administrator shall screen substances and designate high-priority substances taking into consideration the ability of the Administrator to schedule and complete safety assessments and safety determinations under section 6 in a timely manner.

"(II) ANNUAL GOAL.—The Administrator shall publish an annual goal for the number of chemical substances to be subject to the prioritization screening process.

"(C) SCREENING OF CATEGORIES OF SUBSTANCES.—The Administrator may screen categories of chemical substances to ensure an efficient prioritization screening process to allow for timely and adequate designations of high-priority substances and low-priority substances and safety assessments and safety determinations for high-priority substances.

"(D) PUBLICATION OF LIST OF CHEMICAL SUBSTANCES.—Not less frequently than once each year, the Administrator shall publish a list of chemical substances that—

"(i) are being considered in the prioritization screening process and the status of the chemical substances in the prioritization process, including those chemical substances for which prioritization decisions have been deferred; and

"(ii) are designated as high-priority substances or low-priority substances, including the bases for such designations.

"(4) CRITERIA.—The criteria described in paragraph (1) shall account for—

"(A) the recommendation of the Governor of a State or a State agency with responsibility for protecting health or the environment from chemical substances appropriate for prioritization screening;

"(B) the hazard and exposure potential of the chemical substance (or category of substances), including persistence, bioaccumulation, and specific scientific classifications and designations by authoritative governmental entities;

"(C) the conditions of use or significant changes in the conditions of use of the chemical substance;

"(D) evidence and indicators of exposure potential to humans or the environment from the chemical substance, including potentially exposed or susceptible populations;

"(E) the volume of a chemical substance manufactured or processed;

"(F) whether the volume of a chemical substance as reported under a rule promulgated pursuant to section 8(a) has significantly increased or decreased during the period beginning on the date of a previous report or the date on which a notice has been submitted under section 5(b) for that chemical substance;

"(G) the availability of information regarding potential hazards and exposures required for conducting a safety assessment or safety determination, with limited availability of relevant information to be a sufficient basis for designating a chemical substance as a high-priority substance, subject to the condition that limited availability shall not require designation as a high-priority substance; and

"(H) the extent of Federal or State regulation of the chemical substance or the extent of the impact of State regulation of the chemical substance on the United States, with existing Federal or State regulation of any uses evaluated in the prioritization screening process as a factor in designating a chemical substance to be a high-priority or a low-priority substance.

"(b) PRIORITIZATION SCREENING PROCESS AND DECISIONS.—

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall include a requirement that the Administrator shall—

"(A) identify the chemical substances being considered for prioritization;

"(B) request interested persons to supply information regarding the chemical substances being considered;

"(C) apply the criteria identified in subsection (a)(4); and

"(D) subject to paragraph (5) and using the information available to the Administrator at the time of the decision, identify a chemical substance as a high-priority substance or a low-priority substance.

"(2) INTEGRATION OF INFORMATION.—The prioritization screening decision regarding a chemical substance shall integrate any hazard and exposure information relating to the chemical substance that is available to the Administrator.

"(3) IDENTIFICATION OF HIGH-PRIORITY SUBSTANCES.—The Administrator—

"(A) shall identify as a high-priority substance a chemical substance that, relative to other active chemical substances, the Administrator determines has the potential for high hazard and widespread exposure;

"(B) may identify as a high-priority substance a chemical substance that, relative to other active chemical substances, the Administrator determines has the potential for high hazard or widespread exposure; and

"(C) may identify as a high-priority substance an inactive substance, as determined under subsection (a)(3)(A)(ii) and section 8(b), that the Administrator determines warrants a safety assessment and safety determination under section 6.

"(4) IDENTIFICATION OF LOW-PRIORITY SUBSTANCES.—The Administrator shall identify as a

low-priority substance a chemical substance that the Administrator concludes has information sufficient to establish that the chemical substance is likely to meet the safety standard.

"(5) DEFERRING A DECISION.—If the Administrator determines that additional information is required to establish the priority of a chemical substance under this section, the Administrator may defer the prioritization screening decision for a reasonable period—

"(A) to allow for the submission of additional information by an interested person and for the Administrator to evaluate the additional information; or

"(B) to require the development of information pursuant to a rule, testing consent agreement, or order issued under section 4(a)(2).

"(6) DEADLINES FOR SUBMISSION OF INFORMATION.—If the Administrator requests the development or submission of information under this section, the Administrator shall establish a deadline for submission of the information.

"(7) NOTICE AND COMMENT.—The Administrator shall—

"(A) publish the proposed decisions made under paragraphs (3), (4), and (5) and the basis for the decisions; and

"(B) provide an opportunity for public comment.

"(8) REVISIONS OF PRIOR DESIGNATIONS.—

"(A) IN GENERAL.—At any time, and at the discretion of the Administrator, the Administrator may revise the designation of a chemical substance as a high-priority substance or a low-priority substance based on information available to the Administrator after the date of the determination under paragraph (3) or (4).

"(B) LIMITED AVAILABILITY.—If limited availability of relevant information was a basis in the designation of a chemical substance as a high-priority substance, the Administrator shall reevaluate the prioritization screening of the chemical substance on receiving the relevant information.

"(9) OTHER INFORMATION RELEVANT TO PRIORITIZATION.—

"(A) IN GENERAL.—If, after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, a State

proposes an administrative action or enacts a statute or takes an administrative action to prohibit or otherwise restrict the manufacturing, processing, distribution in commerce, or use of a chemical substance that the Administrator has not as designated a high-priority substance, the Governor or State agency with responsibility for implementing the statute or administrative action shall notify the Administrator.

"(B) REQUESTS FOR INFORMATION.—Following receipt of a notification provided under subparagraph (A), the Administrator may request any available information from the Governor or the State agency with respect to—

"(i) scientific evidence related to the hazards, exposures and risks of the chemical substance under the conditions of use which the statute or administrative action is intended to address;

"(ii) any State or local conditions which warranted the statute or administrative action;

"(iii) the statutory or administrative authority on which the action is based; and

"(iv) any other available information relevant to the prohibition or other restriction, including information on any alternatives considered and their hazards, exposures, and risks.

"(C) PRIORITIZATION SCREENING.—The Administrator shall conduct a prioritization screening under this subsection for all substances that—

"(i) are the subject of notifications received under subparagraph (A); and

"(ii) the Administrator determines—

"(I) are likely to have significant health or environmental impacts;

"(II) are likely to have significant impact on interstate commerce; or

"(III) have been subject to a prohibition or other restriction under a statute or administrative action in 2 or more States.

"(D) AVAILABILITY TO PUBLIC.—Subject to section 14 and any applicable State law regarding the protection of confidential information provided to the State or to the Adminis-

trator, the Administrator shall make information received from a Governor or State agency under subparagraph (A) publicly available.

"(E) EFFECT OF PARAGRAPH.—Nothing in this paragraph shall preempt a State statute or administrative action, require approval of a State statute or administrative action, or apply section 15 to a State.

"(10) REVIEW.—Not less frequently than once every 5 years after the date on which the process under this subsection is established, the Administrator shall—

"(A) review the process on the basis of experience and taking into consideration resources available to efficiently and effectively screen and prioritize chemical substances; and

"(B) if necessary, modify the prioritization screening process.

"(11) EFFECT.—Subject to section 18, a designation by the Administrator under this section with respect to a chemical substance shall not affect—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance; or

"(B) the regulation of those activities.

"(c) ADDITIONAL PRIORITIES FOR SAFETY ASSESSMENTS AND DETERMINATIONS.—

"(1) IN GENERAL.—The prioritization screening process developed under subsection (a) shall—

"(A) include a process by which a manufacturer or processor of an active chemical substance that has not been designated a high-priority substance or is not in the process of a prioritization screening by the Administrator, may request that the Administrator designate the substance as an additional priority for a safety assessment and safety determination, subject to the payment of fees pursuant to section 26(b)(3)(E);

"(B) specify the information to be provided in such requests; and

"(C) specify the criteria the Administrator shall use to determine whether or not to grant such a request, which shall include whether the substance is subject to restrictions imposed by statutes enacted or administrative actions taken by 1 or more States on the manufacture, processing, distribution in commerce, or use of the substance.

"(2) PREFERENCE.—Subject to paragraph (3), in deciding whether to grant requests under this subsection the Administrator shall give a preference to requests concerning substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

"(3) LIMITATIONS.—In considering whether to grant a request submitted under paragraph (1), the Administrator shall ensure that—

"(A) not more than 15 percent of the total number of substances designated to undergo safety assessments and safety determinations under this section are substances designated under the process and criteria pursuant to paragraph (1); and

"(B) the resources allocated to conducting safety assessments and safety determinations for additional priorities designated under this subsection are proportionate to the number of such substances relative to the total number of substances designated to undergo safety assessments and safety determinations under this section.

"(4) REQUIREMENTS.—

"(A) IN GENERAL.—The public shall be provided notice and an opportunity to comment on requests submitted under this subsection.

"(B) DECISION BY ADMINISTRATOR.—Not later than 180 days after the date on which the Administrator receives a request under this subsection, the Administrator shall decide whether or not to grant the request.

"(C) ASSESSMENT AND DETERMINATION.—If the Administrator grants a request under this subsection, the safety assessment and safety determination—

"(i) shall be conducted in accordance with the deadlines and other requirements of sections 3A(i) and 6; and

"(ii) shall not be expedited or otherwise subject to special treatment relative to high-priority substances designated pursuant to subsection (b)(3) that are undergoing safety assessments and safety determinations.

"(5) EXCEPTIONS.—Requests granted under this subsection shall not be subject to subsection (a)(3)(A)(iii) or section 18(b).".

SEC. 7. NEW CHEMICALS AND SIGNIFICANT NEW USES.

Section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 5. NEW CHEMICALS AND SIGNIFICANT NEW USES.";

(2) by striking subsection (b);

(3) by redesignating subsection (a) as subsection (b);

(4) by redesignating subsection (i) as subsection (a) and moving the subsection so as to appear at the beginning of the section;

(5) in subsection (b) (as so redesignated)—

(A) in the subsection heading, by striking "IN GENERAL" and inserting "NOTICES"; and

(B) in paragraph (1), in the matter following subparagraph (B)—

(i) by striking "subsection (d)" and inserting "subsection (b)"; and

(ii) by striking "and such person complies with any applicable requirement of subsection (b)";

(6) by redesignating subsections (c) and (d) as subsection (d) and (e), respectively, and moving subsection (c) (as so redesigned) so as appear after subsection (b) (as redesignated by paragraph (3));

(7) in subsection (c) (as so redesignated)—

(A) by striking paragraph (1) and inserting the following:

"(1) IN GENERAL.—The notice required by subsection (a) shall include, with respect to a chemical substance—

"(A) the information required by sections 720.45 and 720.50 of title 40, Code of Federal Regulations (or successor regulations); and

"(B) information regarding conditions of use and reasonably anticipated exposures.";

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking "or of data under subsection (b)";

(ii) in subparagraph (A), by adding "and" after the semicolon at the end;

(iii) in subparagraph (B), by striking "; and" and inserting a period; and

(iv) by striking subparagraph (C); and

(C) in paragraph (3), by striking "subsection (a) and for which the notification period prescribed by subsection (a), (b), or (c)" and inserting "subsection (b) and for which the no-

tification period prescribed by subsection (b) or (d)";

(8) by striking subsection (d) (as redesignated by paragraph (6)) and inserting the following:

"(d) REVIEW OF NOTICE.—

"(1) INITIAL REVIEW.—

"(A) IN GENERAL.—Subject to subparagraph (B), not later than 90 days after the date of receipt of a notice submitted under subsection (b), the Administrator shall—

"(i) conduct an initial review of the notice;

"(ii) as needed, develop a profile of the relevant chemical substance and the potential for exposure to humans and the environment; and

"(iii) make any necessary determination under paragraph (3).

"(B) EXTENSION.—Except as provided in paragraph (5), the Administrator may extend the period described in subparagraph (A) for good cause for 1 or more periods, the total of which shall be not more than 90 days.

"(2) INFORMATION SOURCES.—In evaluating a notice under paragraph (1), the Administrator shall take into consideration—

"(A) any relevant information identified in subsection (c)(1); and

"(B) any other relevant additional information available to the Administrator.

"(3) DETERMINATIONS.—Before the end of the applicable period for review under paragraph (1), based on the information described in paragraph (2), and subject to section 18(g), the Administrator shall determine that—

"(A) the relevant chemical substance or significant new use is not likely to meet the safety standard, in which case the Administrator shall take appropriate action under paragraph (4);

"(B) the relevant chemical substance or significant new use is likely to meet the safety standard, in which case the Administrator shall allow the review period to expire without additional restrictions; or

"(C) additional information is necessary in order to make a determination under subparagraph (A) or (B), in which case the Adminis-

trator shall take appropriate action under paragraph (5).

"(4) RESTRICTIONS.—

"(A) DETERMINATION BY ADMINISTRATOR.—

"(i) IN GENERAL.—If the Administrator makes a determination under subparagraph (A) or (C) of paragraph (3) with respect to a notice submitted under subsection (b)—

"(I) the Administrator, before the end of the applicable period for review under paragraph (1) and by consent agreement or order, as appropriate, shall prohibit or otherwise restrict the manufacture, processing, use, distribution in commerce, or disposal (as applicable) of the chemical substance, or of the chemical substance for a significant new use, without compliance with the restrictions specified in the consent agreement or order that the Administrator determines are sufficient to ensure that the chemical substance or significant new

use is likely to meet the safety standard; and

"(II) no person may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, except in compliance with the restrictions specified in the consent agreement or order.

"(ii) LIKELY TO MEET STANDARD.—If the Administrator makes a determination under subparagraph (B) of paragraph (3) with respect to a chemical substance or significant new use for which a notice was submitted under subsection (b), at the end of the applicable period for review under paragraph (1), the submitter of the notice may commence manufacture for commercial purposes of the chemical substance or manufacture or processing of the chemical substance for a significant new use.

"(B) REQUIREMENTS.—Not later than 90 days after issuing a consent agreement or order under subparagraph (A), the Administrator shall—

"(i) take into consideration whether to promulgate a rule pursuant to subsection (b)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance, or of the chemical substance for a new use, that is not in compliance with the restrictions imposed by the consent agreement or order; and

"(ii)(I) initiate a rulemaking described in clause (i); or

"(II) publish a statement describing the reasons of the Administrator for not initiating a rulemaking.

"(C) INCLUSIONS.—A prohibition or other restriction under subparagraph (A) may include, as appropriate—

"(i) subject to section 18(g), a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and in-

structions to be prescribed by the Administrator

"(ii) a requirement that manufacturers or processors of the chemical substance shall—

"(I) make and retain records of the processes used to manufacture or process, as applicable, the chemical substance; or

"(II) monitor or conduct such additional tests as are reasonably necessary to address potential risks from the manufacture, processing, distribution in commerce, use, or disposal, as applicable, of the chemical substance, subject to section 4;

"(iii) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce—

"(I) in general; or

"(II) for a particular use;

"(iv) a prohibition or other restriction of—

"(I) the manufacture, processing, or distribution in commerce of the chemical substance for a significant new use;

"(II) any method of commercial use of the chemical substance; or

"(III) any method of disposal of the chemical substance; or

"(v) a prohibition or other restriction on the manufacture, processing, or distribution in commerce of the chemical substance—

"(I) in general; or

"(II) for a particular use.

"(D) MITIGATION.—In selecting among prohibitions and restrictions to address an identified potential risk, the Administrator shall apply prohibitions or restrictions to articles on the basis of a chemical substance or mixture contained in the article only to the extent necessary to mitigate the identified potential risk.

"(E) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or

other restriction under this subsection to address workplace exposures.

"(F) DEFINITION OF REQUIREMENT.—For purposes of this Act, the term 'requirement' as used in this section does not displace common law.

"(5) ADDITIONAL INFORMATION.—If the Administrator determines under paragraph (3)(C) that additional information is necessary to conduct a review under this subsection, the Administrator—

"(A) shall provide an opportunity for the submitter of the notice to submit the additional information;

"(B) may, by agreement with the submitter, extend the review period for a reasonable time to allow the development and submission of the additional information;

"(C) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information; and

"(D) on receipt of information the Administrator finds supports the determination under paragraph (3), shall promptly make the determination.";

(9) by striking subsections (e) through (g) and inserting the following:

"(e) NOTICE OF COMMENCEMENT.—

"(1) IN GENERAL.—Not later than 30 days after the date on which a manufacturer that has submitted a notice under subsection (b) commences nonexempt commercial manufacture of a chemical substance, the manufacturer shall submit to the Administrator a notice of commencement that identifies—

"(A) the name of the manufacturer; and

"(B) the initial date of nonexempt commercial manufacture.

"(2) WITHDRAWAL.—A manufacturer or processor that has submitted a notice under subsection (b), but that has not commenced nonexempt commercial manufacture or processing of the chemical substance, may withdraw the notice.

"(f) FURTHER EVALUATION.—The Administrator may review a chemical substance under section 4A at any time after the Administrator receives—

"(1) a notice of commencement for a chemical substance under subsection (c); or

"(2) new information regarding the chemical substance.

"(g) TRANSPARENCY.—Subject to section 14, the Administrator shall make available to the public—

"(1) all notices, determinations, consent agreements, rules, and orders of the Administrator; and

"(2) all information submitted or issued under this section."; and

(10) in subsection (h)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking "(a) or";

(B) by striking paragraph (2);

(C) by redesignating paragraphs (3) through (6) as paragraphs (2) through (5), respectively;

(D) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking "subsections (a) and (b)" and inserting "subsection (b)";

(E) in paragraph (3) (as so redesignated)—

(i) in the first sentence, by striking "will not present an unreasonable risk of injury to health or the environment" and inserting "will meet the safety standard"; and

(ii) by striking the second sentence;

(F) in paragraph (4) (as so redesignated), by striking "subsections (a) and (b)" and inserting "subsection (b)"; and

(G) in paragraph (5) (as so redesignated), in the first sentence, by striking "paragraph (1) or (5)" and inserting "paragraph (1) or (4)".

SEC. 8. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section designation and heading and inserting the following:

"SEC. 6. SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS.";

(2) by redesignating subsections (e) and (f) as subsections (g) and (h), respectively;

(3) by striking subsections (a) through (d) and inserting the following:

"(a) IN GENERAL.—The Administrator—

"(1) shall conduct a safety assessment and make a safety determination of each high-priority substance in accordance with subsections (b) and (c);

"(2) shall, as soon as practicable and not later than 6 months after the date on which a chemical

substance is designated as a high-priority substance, define the scope of the safety assessment and safety determination to be conducted pursuant to this section, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that the Administrator expects to consider;

"(3) as appropriate based on the results of a safety determination, shall establish restrictions pursuant to subsection (d);

"(4) shall complete a safety assessment and safety determination not later than 3 years after the date on which a chemical substance is designated as a high-priority substance;

"(5) shall promulgate a final rule pursuant to subsection (d) by not later than 2 years after the date on which the safety determination is completed; and

"(6) may extend any deadline under this subsection for a reasonable period of time after an adequate public justification, subject to the condition that the aggregate length of all extensions of deadlines under paragraphs (4) and (5) and any deferral under subsection (c)(2) does not exceed 2 years.

"(b) PRIOR ACTIONS.—

"(1) PRIOR-INITIATED ASSESSMENTS.—

"(A) IN GENERAL.—Nothing in this Act prevents the Administrator from initiating a safety assessment or safety determination regarding a chemical substance, or from continuing or completing such a safety assessment or safety determination that was initiated before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, prior to the effective date of the policies and procedures required to be established by the Administrator under section 3A or 4A.

"(B) INTEGRATION OF PRIOR POLICIES AND PROCEDURES.—As policies and procedures under section 3A and 4A are established, to the maximum extent practicable, the Administrator shall integrate the policies and procedures into ongoing safety assessments and safety determinations.

"(2) ACTIONS COMPLETED PRIOR TO COMPLETION OF POLICIES AND PROCEDURES.—Nothing in this Act requires the Administrator to revise or withdraw a completed safety assessment, safety determination, or rule solely because the action was completed prior to the completion of a policy or procedure established under section 3A or 4A, and the va-

lidity of a completed assessment, determination, or rule shall not be determined based on the content of such a policy or procedure.

"(c) SAFETY DETERMINATIONS.—

"(1) IN GENERAL.—Based on a review of the information available to the Administrator, including draft safety assessments submitted by interested persons, and subject to section 18, the Administrator shall determine that—

"(A) the relevant chemical substance meets the safety standard;

"(B) the relevant chemical substance does not meet the safety standard, in which case the Administrator shall, by rule under subsection (d)—

"(i) impose restrictions necessary to ensure that the chemical substance meets the safety standard under the conditions of use; or

"(ii) if the safety standard cannot be met with the application of restrictions, ban or phase out the chemical substance, as appropriate; or

"(C) additional information is necessary in order to make a determination under subpara-

graph (A) or (B), in which case the Administrator shall take appropriate action under paragraph (2).

"(2) ADDITIONAL INFORMATION.—If the Administrator determines that additional information is necessary to make a safety assessment or safety determination for a high-priority substance, the Administrator—

"(A) shall provide an opportunity for interested persons to submit the additional information;

"(B) may promulgate a rule, enter into a testing consent agreement, or issue an order under section 4 to require the development of the information;

"(C) may defer, for a reasonable period consistent with the deadlines described in subsection (a), a safety assessment and safety determination until after receipt of the information; and

"(D) consistent with the deadlines described in subsection (a), on receipt of information the Administrator finds supports the safety assessment and safety determination, shall make a determination under paragraph (1).

"(3) ESTABLISHMENT OF DEADLINE.—In requesting the development or submission of information under this section, the Administrator shall establish a deadline for the submission of the information.

"(d) RULE.—

"(1) IMPLEMENTATION.—If the Administrator makes a determination under subsection (c)(1)(B) with respect to a chemical substance, the Administrator shall promulgate a rule establishing restrictions necessary to ensure that the chemical substance meets the safety standard.

"(2) SCOPE.—

"(A) IN GENERAL.—The rule promulgated pursuant to this subsection—

"(i) may apply to mixtures containing the chemical substance, as appropriate;

"(ii) shall include dates by which compliance is mandatory, which—

"(I) shall be as soon as practicable; and

"(II) as determined by the Administrator, may vary for different affected persons; and

"(iii) shall—

"(I) exempt replacement parts that are manufactured prior to the effective date of the rule for articles that are first manufactured prior to the effective date of the rule unless the Administrator finds the replacement parts contribute significantly to the identified risk; and

"(II) in selecting among prohibitions and restrictions to address an identified risk, apply prohibitions or restrictions to articles on the basis of a chemical substance or mixture contained in the article only to the extent necessary to mitigate the identified risk.

"(B) WORKPLACE EXPOSURES.—The Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health before adopting any prohibition or other restriction under this subsection to address workplace exposures.

"(C) DEFINITION OF REQUIREMENT.—For the purposes of this Act, the term 'requirement'

as used in this section does not displace common law.

"(3) RESTRICTIONS.—A restriction under paragraph (1) may include, as appropriate—

"(A) subject to section 18, a requirement that a chemical substance shall be marked with, or accompanied by, clear and adequate minimum warnings and instructions with respect to use, distribution in commerce, or disposal, or any combination of those activities, with the form and content of the minimum warnings and instructions to be prescribed by the Administrator;

"(B) a requirement that manufacturers or processors of the chemical substance shall—

"(i) make and retain records of the processes used to manufacture or process the chemical substance;

"(ii) describe and apply the relevant quality control procedures followed in the manufacturing or processing of the substance; or

"(iii) monitor or conduct tests that are reasonably necessary to ensure compli-

ance with the requirements of any rule under this subsection;

"(C) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce;

"(D) a requirement to ban or phase out, or any other rule regarding, the manufacture, processing, or distribution in commerce of the chemical substance for—

"(i) a particular use;

"(ii) a particular use at a concentration in excess of a level specified by the Administrator; or

"(iii) all uses;

"(E) a restriction on the quantity of the chemical substance that may be manufactured, processed, or distributed in commerce for—

"(i) a particular use; or

"(ii) a particular use at a concentration in excess of a level specified by the Administrator;

"(F) a requirement to ban, phase out, or otherwise restrict any method of commercial use of the chemical substance;

"(G) a requirement to ban, phase out, or otherwise restrict any method of disposal of the chemical substance or any article containing the chemical substance; and

"(H) a requirement directing manufacturers or processors of the chemical substance to give notice of the Administrator's determination under subsection (c)(1)(B) to distributors in commerce of the chemical substance and, to the extent reasonably ascertainable, to other persons in the chain of commerce in possession of the chemical substance.

"(4) ANALYSIS FOR RULEMAKING.—

"(A) CONSIDERATIONS.—In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

"(B) ALTERNATIVES.—As part of the analysis, the Administrator shall review any 1

or more technically and economically feasible alternatives to the chemical substance that the Administrator determines are relevant to the rulemaking.

"(C) PUBLIC AVAILABILITY.—In proposing a rule under paragraph (1), the Administrator shall make publicly available any analysis conducted under this paragraph.

"(D) STATEMENT REQUIRED.—In making final a rule under paragraph (1), the Administrator shall include a statement describing how the analysis considered under subparagraph (A) was taken into account.

"(5) EXEMPTIONS.—

"(A) IN GENERAL.—The Administrator may exempt 1 or more uses of a chemical substance from any restriction in a rule promulgated under paragraph (1) if the Administrator determines that—

"(i) the rule cannot be complied with, without—

"(I) harming national security;

"(II) causing significant disruption in the national economy due to

the lack of availability of a chemical substance; or

"(III) interfering with a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; or

"(ii) the use of the chemical substance, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

"(B) EXEMPTION ANALYSIS.—In proposing a rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall make publicly available any analysis conducted under this paragraph to assess the need for the exemption.

"(C) STATEMENT REQUIRED.—In making final a rule under paragraph (1) that includes an exemption under this paragraph, the Administrator shall include a statement describing how the analysis considered under subparagraph (B) was taken into account.

"(D) ANALYSIS IN CASE OF BAN OR PHASE-OUT.—In determining whether an exemption should be granted under this paragraph for a chemical substance for which a ban or phase-out is proposed, the Administrator shall take into consideration, to the extent practicable based on reasonably available information, the quantifiable and nonquantifiable costs and benefits of the 1 or more technically and economically feasible alternatives to the chemical substance most likely to be used in place of the chemical substance under the conditions of use if the rule is promulgated.

"(E) CONDITIONS.—As part of a rule promulgated under paragraph (1), the Administrator shall include conditions in any exemption established under this paragraph, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption.

"(F) DURATION.—

"(i) IN GENERAL.—The Administrator shall establish, as part of a rule under

paragraph (1) that contains an exemption under this paragraph, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis.

"(ii) AUTHORITY OF ADMINISTRATOR.—The Administrator, by rule, may extend, modify, or eliminate the exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or is no longer necessary.

"(iii) CONSIDERATIONS.—

"(I) IN GENERAL.—Subject to subclause (II), the Administrator shall issue exemptions and establish time periods by considering factors determined by the Administrator to be relevant to the goals of fostering innovation and the development of alternatives that meet the safety standard.

"(II) LIMITATION.—Any renewal of an exemption in the case of a rule requiring the ban or phase-out of a

chemical substance shall not exceed 5 years.

"(e) IMMEDIATE EFFECT.—The Administrator may declare a proposed rule under subsection (d)(1) to be effective on publication of the rule in the Federal Register and until the effective date of final action taken respecting the rule, if—

"(1) the Administrator determines that—

"(A) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to the proposed rule or any combination of those activities is likely to result in an unreasonable risk of serious or widespread harm to health or the environment before the effective date; and

"(B) making the proposed rule so effective is necessary to protect the public interest; and

"(2) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under paragraph (1)(A), a court has granted relief in an action under section 7 with respect to that risk associated with the chemical substance or mixture.